8–22–08 Friday
Vol. 73 No. 164 Aug. 22, 2008

Pages 49591–49932

Federal Register

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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Washington, DC 20002

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DEPARTMENT OF AGRICULTURE

Rural Housing Service

7 CFR Part 3550

RIN 0575–AC69

Direct Single Family Housing Loans and Grants

AGENCY: Rural Housing Service, USDA.

ACTION: Direct final rule.

SUMMARY: Through this action, Rural Housing Service (RHS) is addressing the following:

The Agency is revising the minimum insurance deductible amount and removing specific dollar limits with regards to insurance deductible clauses. The Agency also is clarifying the amount of dwelling coverage required to address current standards in the mortgage insurance industry and the coverage that the Agency may obtain when force-placed insurance is required. The intended effect is to make it easier for new homeowners to secure affordable insurance coverage and give the Agency sufficient flexibility to quickly react to changes in insurance costs and requirements.

This action also is revising the applicant net asset limitation to increase it from $7,500 to $15,000 for non-elderly families and from $10,000 to $20,000 for elderly families. The intended effect is to require applicants to contribute a downpayment when their net assets exceed the stated limits. These limits have not been updated in over 10 years.

Finally, this action updates the rural area definition to reference the effective date of census data collected through 2010.

This rule combines three actions under one notice. In the event that we receive adverse comments on any one section of this rule, we will proceed with the final implementation of the other portions not affected. No adverse comments are anticipated.

DATES: This rule is effective without further action November 5, 2008 unless we receive written adverse comments or written notices of intent to submit adverse comments on or before October 21, 2008. If adverse comment is received, RHS will publish a timely withdrawal of the rule in the **Federal Register**.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Submit written comments via the U.S. Postal Service to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, STOP 0742, 1400 Independence Avenue, SW., Washington, DC 20250–0742.
- *Hand Delivery/Courier:* Submit written comments via Federal Express Mail or another mail courier service requiring a street address to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, 300 7th Street, SW., 7th Floor, Suite 701, Washington, DC 20024.

All written comments will be available for public inspection during regular work hours at the 300 7th Street, SW., address listed above.

FOR FURTHER INFORMATION CONTACT: Teresa Sumpter, Loan Specialist, Rural Housing Service, Single Family Housing Direct Loan Division, Stop 0783, 1400 Independence Avenue, SW., Washington, DC 20250–0783; Telephone: 202–720–1474; FAX: 202–720–2232; e-mail: *Teresa.Sumpter@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Classification

This rule has been determined to be not significant and was not reviewed by the Office of Management and Budget (OMB) under Executive Order 12866.

Paperwork Reduction Act of 1995

The information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of 44 U.S.C. chapter 35 and have been assigned OMB control number 0575–0172, in accordance with the Paperwork Reduction Act (PRA) of 1995. This rule does not impose any new or modified information collection requirements.

E-Government Act Compliance

The Rural Housing Service is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Civil Justice Reform

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. In accordance with that Executive Order: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings in accordance with the regulations of the National Appeals Division of USDA at 7 CFR part 11 must be exhausted before bringing suit in court challenging action taken under this rule unless those regulations specifically allow bringing suit at an earlier time.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, 2 U.S.C. 1532, RHS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires RHS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, and tribal Governments, or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Programs Affected

The programs affected by this final rule are 10.410 Very Low to Moderate Income Housing Loans and 10.417 Very Low-Income Housing Repair Loans and Grants.

Intergovernmental Consultation

For the reasons set forth in the final rule to 7 CFR part 3015, subpart V, and related notice (48 FR 29115) this program is not subject to Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, ''Environmental Program.'' It is the determination of RHS that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act of 1969, Public Law 91–190, an Environmental Impact Statement is not required.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The programs affected by this rule provide loans and grants to individuals. For this reason, the undersigned has determined and certified by signature of this document that this rule will not have a significant economic impact on a substantial number of small entities. This rulemaking action does not involve a new or expanded program.

Federalism

The policies contained in this rule do not have any substantial direct effect on States, on the relationship between the National government and the States, or on the distribution of power and responsibilities among the various levels of government. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Background

1. According to 7 CFR 3550.61(b) and 7 CFR 3550.110(b), the dwelling and any other essential buildings must be insured in an amount that is the lesser of the insurable value (cost of restoration) or the balance of the secured principal debt. Many companies are reluctant to issue policies when the coverage is well in excess of the replacement value of the home. This is a particular problem in areas with high windstorm and water damage that make it extremely difficult for borrowers/homeowners to secure affordable insurance coverage and almost impossible to pay the rates if they are located in a high risk area that may be subject to disasters such as hurricanes and tornadoes. New borrowers have escrow accounts set up that collect the insurance premium.

Agency borrowers with loans made before escrow was available, prior to September 1996 when the Agency began centralized servicing of its portfolio, normally provide their own coverage. When a homeowner fails to provide insurance, the government force-places insurance coverage typically in the last known insured amount. This assures that the Government's interests are protected and provides our customers the best opportunity to become successful homeowners. Force place insurance only provides insurance coverage to the Agency and does not provide any direct coverage or benefit to the borrower.

With this action, the Agency is revising 7 CFR sections 3550.61 and 3550.110 (Section 502 requests) to clarify the minimum insurance deductible amount, remove specific dollar limits with regards to insurance deductible clauses and clarify that borrowers with a secured indebtedness of $15,000 at the time of loan approval must secure and continually maintain hazard insurance coverage adequate to cover the government's interest for the entire unpaid debt. Loss deductible clauses for required insurance coverage may not exceed generally accepted minimums based on current industry standards and local market conditions. These minimums will be established in the Agency handbook and available in any local Rural Development office. The intended effect is to make it easier for new homeowners to obtain affordable insurance coverage while allowing the Agency sufficient flexibility to quickly update its handbook guidance on insurance deductibles in order to react to changes in insurance costs and requirements and assure the Government's interest in the property is adequately protected.

2. 7 CFR 3550.64 and 7 CFR 3550.103(e) (Section 504 requests) require elderly families with net family assets in excess of $10,000 and non-elderly families with net family assets in excess of $7,500 to apply the excess amount towards the down payment on the property. This limitation has not been updated in over 10 years. U.S. non-metropolitan median income has increased from $33,200 in 1997 to $48,201 in 2006. While these figures indicate a rise in the median income, it should be noted that the dollar value of the net family assets would be similarly higher in dollars without a significant change in composition due to inflation over a long period of time. Thus, as households earn more money, they also must spend more. Based on this information, the Agency believes it is reasonable to relax the down payment requirements. In addition, many elderly applicants in this program are on fixed incomes and have set aside funds and/or purchased financial instruments intended to be used to cover final expenses. The increase in the threshold amounts would allow these elderly applicants to maintain more funds for this purpose. Therefore, we propose to revise the regulation to increase the applicant net family asset limitation from $7,500 to $15,000 for non-elderly families and from $10,000 to $20,000 for elderly families.

3. Finally, the rural area definition will be amended to comply with a change in Section 520 of the Housing Act of 1949 made by Public Law 106–569, Section 705 (December 27, 2000) that extends the grandfathering of areas classified as a rural area prior to October 1, 1990, through receipt of decennial census data for the year 2010 if the area has a population between 10,000 and 25,000, is rural in character, and has a serious lack of credit for lower and moderate income families.

List of Subjects in 7 CFR Part 3550

Accounting, Grant programs, Housing and community development, Housing, Loan programs, Low and moderate income housing, Manufactured homes, Reporting and recordkeeping requirements, Rural areas, Subsidies.

■ For the reasons stated in the preamble, chapter XXXV, Title 7 of the Code of Federal Regulations, is amended as follows:

PART 3550—DIRECT SINGLE FAMILY HOUSING LOANS AND GRANTS

■ 1. The authority citation for part 3550 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 1480.

Subpart A—General

■ 2. Section 3550.10 is amended in paragraph (3) of the definition for ''Rural area'' by replacing ''2000'' with ''2010.''

Subpart B—Section 502 Origination

■ 3. Section 3550.61 is amended by revising the section heading and paragraphs (a), (b) and (d)(1) to read as follows:

§ 3550.61 Insurance (loans only).

(a) Borrower responsibility. Any borrower with a secured indebtedness in excess of $15,000 at the time of loan approval must furnish and continually maintain hazard insurance on the security property, with companies, in amounts, and on terms and conditions acceptable to RHS including a ''loss payable clause'' payable to RHS to protect the Government's interest.

(b) Amount. The borrower is required to insure the dwelling and any other essential buildings in an amount equal to the insurable value of the dwelling and other essential buildings. However, in cases where the borrower's outstanding secured indebtedness is less than the insurable value of the dwelling and other essential buildings, the borrower may elect a lower coverage provided it is not less than the outstanding secured indebtedness. If the borrower fails, or is unable, to insure the secured property, RHS will force place insurance and charge the cost to the borrower's account. Force place insurance only provides insurance coverage to the Agency and does not provide any direct coverage or benefit to the borrower. The amount of the lender-placed coverage will generally be the property's last known insured value.

* * * * *

(d) * * *

(1) Loss deductible clauses for required insurance coverage may not exceed the generally accepted minimums based on current industry standards and local market conditions.

* * * * *

■ 4. Section 3550.64 is revised to read as follows:

§ 3550.64 Down payment.

Elderly families must use any net family assets in excess of $20,000 towards a down payment on the property. Non-elderly families must use net family assets in excess of $15,000 towards a down payment on the property. Applicants may contribute assets in addition to the required down payment to further reduce the amount to be financed.

Subpart C—Section 504 Origination and Section 306C Water and Waste Disposal Grants

■ 6. Section 3550.103 is amended by revising paragraph (e) to read as follows:

§ 3550.103 Eligibility requirements.

* * * * *

(e) *Need and use of personal resources.* Applicants must be unable to obtain financial assistance at reasonable terms and conditions from non-RHS credit or grant sources and lack the personal resources to meet their needs. In cases where the household is experiencing medical expenses in excess of three percent of the household's income, this requirement may be waived or modified. Elderly families must use any net family assets in excess of $20,000 to reduce their section 504 request. Non-elderly families must use any net family assets in excess of $15,000 to reduce their section 504 request. Applicants may contribute assets in excess of the aforementioned amounts to further reduce their request for assistance. The definition of assets for this purpose is net family assets as described in § 3550.54 of subpart B of this part, less the value of the dwelling and a minimum adequate site.

* * * * *

■ 7. Section 3550.110 is amended by revising paragraphs (a), (b) and (d)(1) to read as follows:

§ 3550.110 Insurance (loans only).

(a) Borrower responsibility. Any borrower with a secured indebtedness in excess of $15,000 at the time of loan approval must furnish and continually maintain hazard insurance on the security property, with companies, in amounts, and on terms and conditions acceptable to RHS including a ''loss payable clause'' payable to RHS to protect the Government's interest.

(b) Amount. The borrower is required to insure the dwelling and any other essential buildings in an amount equal to the insurable value of the dwelling and other essential buildings. However, in cases where the borrower's outstanding secured indebtedness is less than the insurable value of the dwelling and other essential buildings, the borrower may elect a lower coverage provided it is not less than the outstanding secured indebtedness. If the borrower fails, or is unable to insure the secured property, RHS will force place insurance and charge the cost to the borrower's account. Force place insurance only provides insurance coverage to the Agency and does not provide any direct coverage or benefit to the borrower. The amount of the lender-placed coverage generally will be the property's last known insured value.

* * * * *

(d) * * *

(1) Loss deductible clauses for required insurance coverage may not exceed the generally accepted minimums based on current and local market conditions.

* * * * *

Dated: July 28, 2008.

Russell T. Davis,

Administrator, Rural Housing Service.

[FR Doc. E8–19350 Filed 8–21–08; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA–1999–F–2405] (formerly 1999F–5522)

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in fresh iceberg lettuce and fresh spinach (hereinafter referred to in this document as ''iceberg lettuce and spinach'') at a dose up to 4.0 kiloGray (kGy). This action is in partial response to a petition filed by The National Food Processors Association on behalf of The Food Irradiation Coalition.

DATES: This rule is effective August 22, 2008. Submit written or electronic objections and requests for a hearing by September 22, 2008. See section VI of this document for information on the filing of objections.

ADDRESSES: You may submit written or electronic objections and requests for a hearing identified by Docket No. FDA–1999–F–2405] (formerly 1999F–5522, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue

to submit electronic objections by using the Federal eRulemaking Portal, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1204.

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I. Background

In a notice published in the **Federal Register** of January 5, 2000 (65 FR 493), and amended May 10, 2001 (66 FR 23943), FDA announced that a food additive petition (FAP 9M4697) had been filed by The National Food Processors Association on behalf of The Food Irradiation Coalition, 1350 I St. NW., suite 300, Washington, DC 20005. The petition proposed that the food additive regulations in part 179, *Irradiation in the Production, Processing, and Handling of Food* (21 CFR part 179), be amended to provide for the safe use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in a variety of human foods up to a maximum irradiation dosage of 4.5 kGy for non-frozen and non-dry products, and 10.0 kGy for frozen or dry products, including: (1) Pre-processed meat and poultry; (2) both raw and pre-processed vegetables, fruits, and other agricultural products of plant origin; (3) certain multi-ingredient food products containing cooked or uncooked meat or poultry. Subsequently, in a letter dated December 4, 2007, the petitioner amended the petition to request a response to part of the original request while the remainder of the request would remain under review. Specifically, the petitioner requested a response regarding amending the food additive regulations to provide for the safe use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in iceberg lettuce and spinach up to a maximum dose of 4.0 kGy. This final rule is a partial response to the petition and addresses only the use of ionizing radiation on iceberg lettuce and spinach. The use of ionizing radiation on the remaining foods included in the petition remains under review.

II. Safety Evaluation

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive. The additive is not added to food literally, but is rather a source of radiation used to process or treat food such that, analogous to other food processing technologies, its use can affect the characteristics of the food. Importantly, the statute does not prescribe the safety tests to be performed but leaves that determination to the discretion and scientific expertise of FDA. Not all food additives require the same amount or type of testing. The testing and data required to establish the safety of an additive will vary depending on the particular additive and its intended use.

In evaluating the safety of a source of radiation to treat food intended for human consumption, the agency must identify the various effects that may result from irradiating the food and assess whether any of these effects pose a public health concern. In doing so, the following three general areas need to be addressed: (1) Potential toxicity, (2) nutritional adequacy, and (3) effects on the microbiological profile of the treated food. Each of these areas is discussed in this document. Because an understanding of radiation chemistry is fundamental in addressing these three areas, key aspects of radiation chemistry relevant to the evaluation of the request that is the subject of this rulemaking are also discussed. FDA has fully considered the data and studies submitted in the petition as well as other data and information relevant to safety.

A. Radiation Chemistry

The term ''radiation chemistry'' refers to the chemical reactions that occur as a result of the absorption of ionizing radiation. In the context of food irradiation, the reactants are the chemical constituents of the food and initial radiolysis products that may undergo further chemical reactions. The chemistry involved in the irradiation of foods has been the subject of numerous studies over the years and scientists have compiled a large body of data regarding the effects of ionizing radiation on different foods under various conditions of irradiation. The basic principles are well understood (Refs. 1 to 4) and provide the basis for extrapolation and generalization from data obtained in specific foods irradiated under specific conditions to draw conclusions regarding foods of a similar type irradiated under different, yet related, conditions. The types and amounts of products generated by radiation-induced chemical reactions (''radiolysis products'') depend on both the chemical constituents of the food and on the specific conditions of irradiation. The principles of radiation chemistry also govern the extent of change, if any, in both the nutrient levels and the microbial loads of irradiated foods.

In the next section, FDA will discuss important aspects of radiation chemistry and related topics as they apply specifically to iceberg lettuce, spinach, and foods of similar composition.

1. Factors Affecting the Radiation Chemistry of Foods

Apart from the chemical composition of the food itself, the specific conditions of irradiation that are most important in considering the radiation chemistry of a given food include the radiation dose, the physical state of the food (e.g., solid or frozen versus liquid or nonfrozen state, dried versus hydrated state), and the ambient atmosphere (e.g., air, reduced oxygen, and vacuum).[1]

The amounts of radiolysis products generated in a particular food are directly proportional to the radiation dose. Therefore, one can extrapolate from data obtained at high radiation

[1] The temperature at which irradiation is conducted can also be a factor, with more radiation-induced changes occuring with increasing temperature. Temperature is less important, however, than the physical state of the food.

doses to draw conclusions regarding the effects at lower doses.

The radiation chemistry of food is strongly influenced by the physical state of the food. If all other conditions, including dose and ambient atmosphere, are the same, the extent of chemical change that occurs in a particular food in the frozen state is less than the change that occurs in the non-frozen state. This is because of the reduced mobility, in the frozen state, of the initial radiolysis products, which will tend to recombine rather than diffuse and react with other food components. Likewise, and for similar reasons, if all other conditions are the same, the extent of chemical change that occurs in the dehydrated state is less than the change that occurs in the fully hydrated state.

The formation of radiolysis products in a given food also is affected by the ambient atmosphere. Irradiation in an atmosphere of high oxygen content generally produces both a greater variety, and greater amounts, of radiolysis products in the food than would be produced in an atmosphere of lower oxygen content. This is because irradiation initiates certain oxidation reactions that occur with greater frequency in foods with high fat content (Refs. 1 and 5).

With few exceptions, the radiolysis products generated in a particular food are the same or very similar to the products formed in other types of food processing or under common storage conditions. These radiolysis products are also typically formed in very small amounts (Ref. 1).

Radiation-induced chemical changes, if sufficiently large, however, may cause changes in the organoleptic properties of the food. Because food processors want to avoid undesirable effects on taste, odor, color, or texture, there is an incentive to minimize the extent of these chemical changes in food. Thus, the doses used to achieve a given technical effect (e.g., inhibition of sprouting, reduction in microorganisms) must be selected carefully to both achieve the intended effect and minimize undesirable chemical changes. Typically, the dose or dose range selected will be the lowest dose practical in achieving the desired effect. Irradiation also is often conducted under reduced oxygen levels or on food held at low temperature or in the frozen state.

2. Radiation Chemistry of the Major Components of Iceberg Lettuce and Spinach

The major components of iceberg lettuce and spinach, as with most fruits and vegetables, are water (approximately 91 to 96 percent) and carbohydrate (up to approximately 4 percent), with protein also present as a minor component. The lipid content of both iceberg lettuce and spinach is quite low (less than 0.5 percent) (Ref. 6).

Because of the high water content of iceberg lettuce and spinach, their radiation chemistry is dominated by the radiation chemistry of water, in which reactive hydroxyl and hydrogen radicals are the primary radiolysis products. These radicals are most likely to recombine to form water, hydrogen gas, or hydrogen peroxide; they may, however, also react with other components of iceberg lettuce and spinach (e.g., carbohydrates). While most of the chemical effects of radiation-processing on iceberg lettuce and spinach are expected to result from the reactions induced by hydroxyl and hydrogen radicals, other food components (e.g., carbohydrates, proteins, and lipids) may also absorb radiation directly and generate small amounts of other radiolysis products.

a. *Carbohydrates*. Carbohydrates are molecules composed of sugar units, which are grouped and categorized according to their size. The simplest and smallest are the monosaccharides (simple sugars such as glucose) and disaccharides (such as sucrose). Larger complex carbohydrates (pectin, fiber, and starch) consist of chains of monosaccharide units and are referred to as polysaccharides. The main effects of ionizing radiation on carbohydrates in foods have been studied extensively and discussed at length in the scientific literature (Refs. 7 and 8), as well as in reviews by such bodies as the World Health Organization (WHO) (Ref. 9). In the presence of water, carbohydrates react primarily with the hydroxyl radicals generated by the radiolysis of water. The result is abstraction of hydrogen from the carbon-hydrogen bonds of the carbohydrate, forming water and a carbohydrate radical. Direct ionization of carbohydrates to form carbohydrate radicals also is possible, but occurs to a far lesser extent (Refs. 10, 11, and 12).

In polysaccharides, the links between constituent monosaccharide units may be broken, resulting in the shortening of polysaccharide chains. Starch may be degraded into dextrins, maltose, and glucose. Sugar acids, ketones, aldehydes, and other sugar monosaccharides may also be formed as a result of ionizing radiation. Various studies have reported that radiolysis products formed from starches of different origin are qualitatively similar. The nature and concentration of the main radiation-induced products showed no marked differences among the various starches. In addition, 40 different products have been analyzed in irradiated starches and have been found to be produced by heat treatment or natural oxidation of starch during storage, as well as by irradiation (Refs. 8 and 10).

The overall effects of ionizing radiation on carbohydrates are basically the same as those caused by cooking and other food processing treatments (Refs. 1 and 10). Irradiation of carbohydrates at doses up to 10 kGy has minimal effect on the carbohydrate functionality and the resulting products are smaller carbohydrates or other compounds also produced from carbohydrates through oxidation and/or heat treatment. FDA concludes that no significant change in carbohydrate nutrient value or functionality is expected to occur in iceberg lettuce and spinach irradiated at doses up to 4 kGy.

b. *Proteins*. FDA has previously provided detailed discussions of the radiation chemistry of proteins in its rulemakings on the use of ionizing radiation to treat meat and molluscan shellfish (''the meat rule,'' 62 FR 64107; December 3, 1997, and ''the molluscan shellfish rule,'' 70 FR 48057; August 16, 2005, respectively). Studies conducted with high-protein foods (e.g., meat, poultry, and seafood), have established that most of the radiolysis products derived from food proteins have the same amino acid composition and are altered only in their secondary and tertiary structures (i.e., denatured). These changes are similar to those that occur as a result of heating, but in the case of irradiation, even at doses up to 50 kGy, such changes are far less pronounced and the amounts of reaction products generated are far lower (62 FR 64107; Refs. 10 and 13). FDA concludes that there will be few reaction products generated from the small amounts of protein in iceberg lettuce and spinach and that no significant change in the amino acid composition of these two foods is expected to result from irradiation at doses up to 4.0 kGy.

c. *Lipids*. FDA also has previously provided a detailed discussion of the radiation chemistry of lipids in the meat and molluscan shellfish rules. In summary, a variety of radiolysis products derived from lipids have been identified, including fatty acids, esters, aldehydes, ketones, alkanes, alkenes, and other hydrocarbons (Refs. 1 and 14). Identical or analogous compounds are also found in foods that have not been irradiated. In particular, heating food produces generally the same types of compounds, but in amounts far greater

than the trace amounts produced from irradiating food (Refs. 10 and 15).

There is, however, a class of radiolysis products derived from lipids, 2-alkylcyclobutanones (2–ACBs), that has been reported to form in small quantities when fats are exposed to ionizing radiation, but not when they are exposed to heat or other forms of processing. The specific 2–ACBs formed will depend on the fatty acid composition of the food. For example, 2-dodecylcyclobutanone (2–DCB) is a radiation by-product of tryiglycerides with esterified palmitic acid. Researchers have reported that 2–DCB is formed in small amounts (less than 1 microgram per gram lipid per kGy (μg/g lipid/kGy) from irradiated chicken (Ref. 16) and in even smaller amounts from ground beef (Ref. 17). Both of these foods are of relatively high total fat and palmitic acid content.[2]

In the molluscan shellfish rule, the agency provided a detailed discussion of its assessment of the significance of the formation of 2–DCB to the safety evaluation of irradiated molluscan shellfish, a food which, like chicken and ground beef, contains significant amounts of triglycerides with esterified palmitic acid. In that assessment, FDA considered all of the available data and information, including the results of genotoxicity studies and previously reviewed studies in which animals were fed diets containing irradiated meat, poultry, and fish. All of these foods contain appreciable amounts of lipids that contain triglycerides with palmitic acid. While 2–DCB and other alkylcyclobutanones would be expected to be present in these irradiated foods, FDA found no evidence of toxicity attributable to their consumption.

As noted previously in this document, iceberg lettuce and spinach contain little fat (less than 0.5 percent); neither food contains appreciable amounts of palmitic acid.[3] Because of the low lipid content and the very low palmitic acid content of iceberg lettuce and spinach, FDA concludes that formation of alkylcyclobutanones generally, and 2–DCB specifically, from irradiation of these foods would be in amounts much smaller than those formed from irradiation of foods of higher fat content and would not pose a toxicological concern.

Overall, FDA concludes that no significant differences are expected to occur between the kinds and amounts of lipids and lipid byproducts in non-irradiated iceberg lettuce and spinach compared to iceberg lettuce and spinach irradiated at doses of 4.0 kGy.

3. Consideration of Furan as a Radiolysis Product

During the course of reviewing the chemical effects of irradiation as part of the evaluation of this and other petitions, FDA became aware of a report that suggested irradiating apple juice may produce furan (Ref. 18). Because furan has been shown to cause tumors in laboratory animals, FDA initiated research on whether the report was accurate and whether furan was a common radiolysis product in food. The petitioner also conducted testing and the United States Department of Agriculture (USDA) initiated additional research. FDA has confirmed that certain foods form furan in low quantities when irradiated. Studies conducted by FDA scientists and other researchers show that some foods form furan when heated and still other foods form furan during storage at refrigeration temperatures (Refs. 19 and 20). Testing of irradiated lettuce and spinach show that if furan is formed when these foods are irradiated, it is formed at levels that are below the limit of detection in the tests, or below the background levels of natural furan formation during storage (Refs. 19, 21, and 22). Therefore, FDA concludes that the consumption of irradiated iceberg lettuce and spinach will not increase the amount of furan in the diet.

B. Toxicological Considerations

The available information from the results of chemical reactions described in section II.A of this document suggests that there is no reason to suspect a toxicological hazard due to consumption of an irradiated food. While chemical analyses have not identified the presence of radiolysis products in amounts that would raise a toxicological concern, the agency notes that the large body of data from studies where irradiated foods were fed to laboratory animals provides an independent way to assess toxicological safety. These studies include those relied on by the agency in previous evaluations of the safety of irradiated foods (see 70 FR 48057, 65 FR 45280, 62 FR 64107, 55 FR 18538, and 51 FR 13376) and additional data and information in FDA files or other published reports regarding studies in which animals were fed a wide variety of foods irradiated at different doses.

The agency's analysis incorporates the principles that toxicological data collected from studies on a given food may be applied to the toxicological evaluation of foods of similar generic class and that data from foods irradiated at high doses can be applied to the toxicological evaluation of foods of similar generic class receiving lower doses (62 FR 64107; Ref. 10). The agency's analysis also draws upon the integrated toxicological database derived from the extensive body of work reviewed by the agency (Ref. 23) and by the WHO[4] in previous evaluations of the safety of irradiated foods. Thus, the agency has re-examined the available data from toxicological studies that are particularly relevant to the safety of irradiated iceberg lettuce and spinach, specifically fruits and vegetables which, as a group, are relatively carbohydrate-rich foods of high water content. The agency's analysis also takes into account the known effects of other conditions of irradiation to compare the results of different studies.

FDA has evaluated a large number of studies in which various irradiated fruits or vegetables,[5] alone or in combination with other irradiated foods, were fed to animals (Refs. 25 and 26). These studies were conducted in a variety of animal species, with foods irradiated at doses ranging from 0.15 to 50 kGy. In the vast majority of these studies, no adverse effects were reported. Three studies reported observations that merit further discussion. FDA has concluded that the effects reported in these three studies were either not attributable to

[2] Beef is generally composed of approximately 15 to 25 percent fat, depending on the cut. Chicken, depending on the cut and whether skin is included, is approximately 5 to 19 percent fat. The palmitic acid content of the fat in beef and chicken is in the range of 22 to 25 percent (Ref. 6)

[3] Iceberg lettuce contains approximately 0.016 percent palmitic acid, and spinach contains approximately 0.046 percent palmitic acid (Ref.6)

[4] During the early 1980s, a joint Food and Agriculture Organization/International Atomic Energy Agency, World Health Organization (FAO/IAEA/WHO) Expert Committee evaluated the toxicological and microbiological safety and nutritional adequacy of irradiated foods. The Expert Committee concluded that irradiation of any food commodity at an average dose of up to 10 kGy presents no toxicological hazard (Ref. 24). In the 1990s, at the request of one of its member states, WHO conducted a new review and analysis of the safety data on irradiated food. This more recent WHO review included all the studies in FDA's files that the agency considered as reasonably complete, as well as those studies that appeared to be acceptable but had deficiencies interfering with the interpretation of the data (see 51 FR 13376 at 13378). The WHO review also included data from USDA and from the Federal Research Centre for Nutrition at Karlsruhe, Germany. WHO concluded that the integrated toxicological database is sufficiently sensitive to evaluate safety and that no adverse toxicological effects due to irradiation were observed in the dose ranges tested (Ref. 9).

[5] The irradiated fruits and vegetables in these studies included: Peaches, strawberries, bananas, cherries, prunes, potatoes, carrots, onions, black beans, corn, green beans, and cabbage.

irradiation or were otherwise not of toxicological significance.

In the first study, dogs fed a diet containing 10 percent onions (dry weight basis, irradiated at 0.25 kGy) for 90 days were reported to develop anemia, as did control dogs fed nonirradiated onions (Ref. 27). Other effects such as increased spleen weights, myeloid metaplasia, and reticuloendothelial hyperplasia were reported but, again, in both control and treated dogs. FDA has concluded that the effects cannot be attributed to irradiation because similar effects were reported in both dogs fed irradiated onions and dogs fed non-irradiated onions (Ref. 25).

The second study was a multi-generation reproduction study in which rats were fed a diet containing 35 percent oranges (dry weight basis) (Ref. 28). Animals in the control group were fed non-irradiated oranges; animals in the treated groups were fed oranges irradiated at 1.40 or 2.79 kGy. The authors reported decreased reproductive performance in the second breeding, as measured by several parameters,[6] for rats fed irradiated oranges as well as those fed the control diet. Because the effects were observed in both animals fed irradiated food and animals fed non-irradiated food, FDA has concluded that they cannot be attributed to irradiation (Refs. 25 and 26). The authors also reported a small, but statistically significant difference in one additional parameter of reproductive performance in treated animals, body weight of pups at weaning. The pups made up for the weight depression after weaning. FDA has concluded that this reported effect is not of toxicological significance for the following two reasons: (1) It was a very small difference in the overall poor reproductive performance of all animals in the second breeding, and (2) the pups from the treated groups made up for the slight weight depression after weaning. In another segment of this study, the authors reported a small, but statistically significant reduction in body weight gain for third generation animals in the treated groups (but not the parent or second generation animals). FDA has concluded that this effect is not of toxicological significance for the following two reasons: (1) There was no apparent dose response,[7] and (2) the differences in body weights were within the normal range of variation for feeding studies (Ref. 26).

In a third study (Ref. 29), weanling rats fed a mixture of cabbage irradiated at 6 kGy and chicken stew irradiated at 56 kGy for 19 days were reported to have reduced levels of alkaline phosphatase in duodenal tissue. In its evaluation of the safety of irradiated meat, FDA reviewed this study in detail and concluded that the effect observed was not of toxicological significance (62 FR 64107 at 64113).

In summary, FDA has reviewed a large body of data relevant to the assessment of potential toxicity of irradiated fruits and vegetables. While all of the studies are not of equal quality or rigor, the agency has concluded that the quantity and breadth of testing and the number and significance of endpoints assessed would have identified any real or meaningful risk. The overwhelming majority of studies showed no evidence of toxicity. On those few occasions when adverse effects were reported, FDA finds that those effects cannot be attributed to irradiation. Based on the totality of the evidence, FDA concludes that irradiation of iceberg lettuce and spinach under the conditions proposed in this petition does not present a toxicological hazard.

C. Nutritional Considerations

It is well known that the nutritive values of the macronutrients in the diet (protein, fats, and carbohydrates) are not significantly altered by irradiation at the petitioned doses (Refs. 30, 31, and 32). Minerals (e.g., calcium and iron) are also unaffected by irradiation. Levels of certain vitamins, on the other hand, may be reduced as a result of irradiation. The extent to which this reduction occurs depends on the specific vitamin, the type of food, and the conditions of irradiation. Not all vitamin loss is nutritionally significant, however, and the extent to which a reduction in a specific vitamin level is significant depends on the relative contribution of the food in question to the total dietary intake of the vitamin.

Nutrition-related information relevant to fruits and vegetables submitted in the petition included analyses of consumption data for these broad categories and of vitamin levels in specific irradiated foods from these categories. The petitioner's overall analysis focused on the the following vitamins the petitioner identified as being present in relatively high levels in fruits and vegetables generally: Thiamine; folate; and vitamins C, E, and A (the latter as provitamin carotenoids). Most of the studies with irradiated fruits or vegetables submitted in the petition focused on the levels of vitamin C or provitamin A carotenoids (sometimes also referred to as carotenes), because fruits and vegetables, as a combined category, are good sources of these micronutrients. Some studies of the effects of irradiation on the levels of vitamin E and on folate were also submitted.

FDA has carefully reviewed the data and information submitted in the petition, as well as other data and information in its files, to determine whether irradiation of iceberg lettuce and spinach would have an adverse effect on the nutritional quality of the diet. FDA's evaluation focused on the effects of irradiation on those nutrients for which at least one of these foods may be identified as an ''excellent source''[8] and for which they contribute more than a trivial amount to the total dietary intake (i.e., greater than 1 to 2 percent)[9]: Vitamin A (from beta-carotene, a provitamin A carotenoid), vitamin K, and folate. FDA's evaluation has also considered the relative radiation sensitivities of these vitamins.

Many fruits and vegetables are good sources of vitamin A (including provitamin A carotenoids). Spinach is considered an excellent source of vitamin A based on its relatively high content of the provitamin A carotenoid beta-carotene. Nevertheless, it contributes no more than 3.5 percent to the total U.S. dietary intake of vitamin A[10] (Refs. 33, 34 and 35).

Although vitamin A has been identified as one of the most radiation-sensitive of the fat-soluble vitamins, carotenoids in plant products demonstrate fairly high resistance to the effects of irradiation. One study of carrots irradiated at 2 kGy reported that carotenoids were stable to irradiation

[6] Incidence of female sterility (percent), established fertility of males (percent), incidence of still births per litter, and pups born alive reaching weaning age (percent).

[7] The effect was more pronounced in rats fed oranges irradiated at the lower of the two test doses, the opposite of what one would expect if the effect were related to irradiation.

[8] In accordance with 21 CFR 101.54(b), foods containing ≥ 20 percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed (RACC), the amount of food customarily consumed per eating occasion such as in one meal or snack) may be labeled as ''excellent source of'', ''high in'' or ''rich in'' a given nutrient. By this criterion, spinach is an excellent source of vitamins A, C, K, and folate. Iceberg lettuce is an excellent source of vitamin K only.

[9] Although spinach contains relatively high amounts of vitamin C, its contribution to the total dietary intake of this vitamin is negligible. The combined group of spinach and ''greens'' (e.g., kale, chard, chives) contributes less than 2 percent to the total dietary intake of vitamin C; the contribution of iceberg lettuce is essentially zero (Ref. 33).

[10] The primary food sources of vitamin A (including provitamin A carotenoids) in the U.S. diet are carrots, organ meats, dairy products, eggs, and ready-to-eat cereals. Together, these food sources contribute approximately 60 percent of the total dietary intake of vitamin A (expressed in retinol equivalents).

and that total carotenoid content of irradiated carrots did not differ from controls through 16 days of storage (Ref. 36). In another study, carotenoid losses in mangoes and papayas irradiated at doses up to 2 kGy were reported to be negligible (0 to 15 percent) while considerable losses resulted from freezing or canning with various additives (Ref. 37). In other studies, minor carotenoid losses in broccoli irradiated at doses of 2 and 3 kGy were observed relative to controls on the day of treatment only, while no marked effects on total carotenoid content of irradiated samples were observed at days 4, 9, and 14 of storage (Ref. 38), and irradiation at doses up to 1 kGy did not affect the total carotenoid content of spinach stored under refrigeration for 15 days (Ref. 39). In several studies, other processing or storage parameters were reported to affect the proportions of individual carotenoids more strongly than irradiation treatment (Ref. 31). FDA concludes that the small losses of vitamin A that might result from the proposed irradiation of iceberg lettuce or spinach will have little impact on the total dietary intake of this vitamin.

Spinach and iceberg lettuce contribute approximately 12 percent and 8 percent, respectively, to the dietary intake of vitamin K (Ref. 40). Vitamin K is widely distributed in other plant and animal foods, however, and deficiencies of vitamin K in humans are extremely rare[11] (Ref. 33).

Vitamin K has also been identified as one of the least radiation sensitive of the fat-soluble vitamins (Ref. 41). In one study, which examined the effects of irradiation, freezing, and canning on vitamin K activity in spinach, along with other vegetables, there was no appreciable radiation-induced loss in Vitamin K activity at doses as high as 28 or 56 kGy, doses much higher than the maximum dose requested in this petition (Ref. 42). FDA concludes that irradiation of iceberg lettuce and spinach up to a maximum dose of 4.0 kGy will have no impact on the total dietary intake of vitamin K (Ref. 33).

Spinach is an excellent source of folate.[12] Nevertheless, in the context of the total diet, spinach contributes only a little more than 2 percent of the total dietary intake of folate (Refs. 33 and 34).[13] Studies that examined radiation-induced losses of folic acid in dehydrated asparagus irradiated to 5 kGy or dehydrated spinach irradiated at 10 kGy found no loss of folate as measured by compositional analysis or in a bioavailability assay in rats (Ref. 43). Another recent study that examined the effects of irradiation of fresh vegetables at 2.5 kGy, reported folate losses of approximately 10 percent in fresh spinach, green cabbage, and Brussels sprouts (Ref. 44). The folate losses observed in this study are comparable to or less than the folate losses that have been reported for vegetables following various heat treatments (Refs. 45 and 46). FDA concludes that radiation-induced loss of folate in iceberg lettuce or spinach will have no significant impact on the dietary intake.

In summary, based on the available data and information, FDA concludes that amending the regulations, as set forth below, to allow for the use of ionizing radiation to treat iceberg lettuce and spinach up to a maximum dose of 4 kGy will not have an adverse impact on the nutritional adequacy of the overall diet.

D. Microbiological Considerations

Leafy green vegetables such as iceberg lettuce or spinach can serve as an ideal habitat for the growth of various microorganisms. Among the common, naturally-occurring microflora of vegetables, *Pseudomonas*, *Enterobacter*, and *Erwinia* species predominate. Various molds and yeasts may also be found on leafy green vegetables. Pathogens, which may also be present in the agricultural environment, can contaminate fresh produce that is grown, harvested, and in some cases undergoes preliminary processing (e.g., cutting or trimming) in that environment. Iceberg lettuce and spinach are often consumed raw and after only minimal preparation (e.g., rinsing) and, therefore, lack the final microbial elimination step provided for other foods by cooking.

Contamination of fresh produce with several specific pathogens continues to be a public health problem. Infections from *Salmonella enterica* serovars and *Escherichia coli* O157:H7, for example, have not decreased since 1996. Most of the recent serious outbreaks of illness attributed to consuming lettuce or spinach have resulted from contamination by *E. coli* O157:H7. Three notable outbreaks involving this microorganism occurred in 2006; one of these was associated with bagged fresh spinach, the other two with lettuce used in fast food restaurants. Contamination of leafy greens with *Listeria monocytogenes* or *Salmonella* serovars also continues to be a public health problem. Even though other pathogens may be present, the three microorganisms named here are those that have been most commonly associated with recent outbreaks from the consumption of raw spinach or lettuce (Ref. 47).

Data and information relevant to microbiological considerations presented in the petition included published studies of radiation-induced reductions in levels of different microorganisms in a variety of fruits and vegetables under different conditions of irradiation. Some of these studies also investigated the use of irradiation in combination with other antimicrobial treatments. FDA has evaluated the information in the petition, along with other data and information in its files and in the published literature in assessing the microbiological issues presented by the petitioner.

There is a large body of work regarding the radiation sensitivities of non-pathogenic food spoilage microorganisms and pathogenic foodborne microorganisms. Generally, the common spoilage organisms such as *Pseudomonas* and the important pathogens in or on leafy greens are quite sensitive to the effects of ionizing radiation. Information in the petition and other information in FDA files shows that *E. coli* O157:H7 is highly sensitive to ionizing radiation, with published D_{10} values[14] ranging from 0.12 to 0.32 kGy, depending on the specific food matrix, physical state of the food, temperature, and other factors. Control of contaminating *Salmonella* serovars or *Listeria* spp. generally requires higher doses than for *E. coli* O157:H7. This is shown by the higher D_{10} values which are in the range of 0.16 to 0.65 kGy, again, depending on the specific food, physical state, temperature, and other factors (Refs. 48 to 51).

Several recent studies have focused on the effects of ionizing radiation on pathogen levels in lettuce and spinach, specifically. In a series of studies by one group of researchers, the average D_{10} values for *E coli* O157:H7 and *L. monocytogenes* were reported to be 0.1 kGy and 0.2 kGy, respectively and the D_{10} value for Salmonella reported to be ca. 0.25–0.3, depending on the lettuce

[11] Other green vegetables such as broccoli, collards, salad greens, and kale contain substantial amounts of vitamin K. Other foods that also contribute to vitamin K intake include: Vegetable oils, grains, liver, cheese, and eggs.

[12] One RACC of raw spinach (85 grams (g) can contain 41 percent of the RDA for folate. One RACC of iceberg lettuce, however, contains only about 6 percent of the RDA for folate; iceberg lettuce is not considered a good source of this vitamin. (Ref. 6)

[13] Enriched and fortified foods (e.g., cereal grains and grain-based products) make the greatest contribution to folate in the diet.

[14] D_{10} is the absorbed dose of radiation required to reduce a bacterial population by 90 percent.

type (Refs. 52 and 53). In another study, treatment with ionizing radiation at a dose of 1.5 kGy produced a 4-$\log_{10}$ reduction in colony-forming units (CFU) on romaine lettuce and a 3-$\log_{10}$ reduction in CFU on baby spinach leaves (Ref. 54). Another recent study examined the effects of irradiation on bagged, ready-to-eat spinach leaves inoculated with E. coli O157:H7 and found that, for single leaves, doses as low as 0.9 kGy resulted in a 5- to 6-$\log_{10}$ reduction in the levels of this pathogen, while a dose of 1.2 kGy resulted in its reduction below the limits of detection of the test (Ref. 39). Collectively, these studies, together with earlier work, establish that levels of *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella* serovars in or on iceberg lettuce or spinach will be reduced by irradiation at dose levels of 0.1 to 1.5 kGy, with the largest reductions occurring at the higher dose levels.

Still other studies have examined the effects of irradiation on extension of shelf life and sensory attributes of various types of vegetables, including iceberg lettuce and spinach. In one study, the authors reported a reduction in total aerobic bacterial counts of over 2-$\log_{10}$ CFU per gram (CFU/g) in fresh-cut lettuce irradiated at 1.0 kGy and over 3-$\log_{10}$ CFU/g reductions at 1.5 kGy (Ref. 55). In a separate study, the same researchers found similar results on total aerobic bacterial counts and significant reductions in coliform counts on fresh-cut lettuce when irradiated with similar doses. In this particular study, the authors also followed numbers of viable bacteria for 9 days storage, noting that for irradiated samples, relative microbial reductions persisted while total numbers of bacteria increased by about 2-$\log_{10}$. Over the same storage period, coliforms remained below the level of detection in irradiated samples (Ref. 56). Recent studies by other researchers have examined the effects of irradiation on levels of pathogens and sensory attributes of fresh-cut iceberg lettuce, including studies in modified atmosphere packaging. One of these studies demonstrated deterioration in several sensory attributes (e.g., firmness, color) when iceberg lettuce is irradiated at levels of 3 or 4 kGy (Ref. 57). Additional related studies on iceberg lettuce and other vegetables by the same group of researchers indicate irradiation above 1.5 or 2 kGy (depending on the specific vegetable) can negatively affect sensory properties (Refs. 58 and 59). Taken together, the studies described above indicate that irradiation in the expected practical dose range will reduce, but not entirely eliminate, spoilage microorganisms.

In evaluating the subject petition, FDA has carefully considered whether irradiation of iceberg lettuce and spinach under the conditions proposed in the petition could result in significantly altered microbial growth patterns such that these foods would present a greater microbiological hazard than comparable food that had not been irradiated. In considering this question, FDA has focused on whether the proposed irradiation conditions would increase the probability of significantly increased growth of, and subsequent toxin production by, *Clostridium botulinum* because this organism is relatively resistant to radiation as compared to non-spore-forming bacteria. FDA has concluded that the possibility of increased microbiological risk from *C. botulinum* is extremely remote because: (1) The conditions of refrigerated storage necessary to maintain the quality of iceberg lettuce or spinach are not amenable to the outgrowth and production of toxin by *C. botulinum* and, (2) sufficient numbers of spoilage organisms will survive such that spoilage will occur before outgrowth and toxin production by *C. botulinum* (Refs. 48 and 60).

Based on the available data and information, FDA concludes that irradiation of iceberg lettuce and spinach conducted in accordance with good manufacturing practices will reduce or eliminate bacterial populations with no increased microbial risk from pathogens that may survive the irradiation process.

III. Comments

FDA has received numerous comments, primarily form letters, from individuals that state their opinions regarding the potential dangers and unacceptability of irradiating food. FDA has also received several comments from individuals or organizations that state their opinions regarding the potential benefits of irradiating food and urging FDA to approve the petition. None of these letters contain any substantive information that can be used in a safety evaluation of irradiated iceberg lettuce and spinach.

Additionally, FDA received several comments from Public Citizen (PC) and the Center for Food Safety (CFS) requesting the denial of this and other food irradiation petitions. Overall, the comments were of a general nature and not necessarily specific to the requests in the individual petitions. Many of these comments from PC and CFS were also submitted to the docket for the agency rulemaking on irradiation of molluscan shellfish (Docket No. 1999F–4372, FAP 9M4682). The topics raised in these comments included the following: Studies reviewed in the 1999 FAO/IAEA/WHO report on high-dose irradiation; a review article that analyzed studies of irradiated foods performed in the 1950's and 1960's; the findings of a 1971 study in which rats were fed irradiated strawberries; the findings regarding reproductive performance in a 1954 study in which mice were fed a special irradiated diet; issues regarding mutagenicity studies; certain international opinions; issues related to ACBs, including purported promotion of colon cancer; the findings of certain studies conducted by the Indian Institute of Nutrition in the 1970's; general issues regarding toxicity data; FDA's purported failure to meet statutory requirements; data from a 2002 study purportedly showing an irradiation-induced increase in trans fatty acids in ground beef; studies regarding purported elevated hemoglobin levels and their significance; and an affidavit describing the opinions of a scientist regarding the dangers of irradiation and advocating the use of alternative methods for reducing the risk of foodborne disease. For a detailed discussion of the agency's response to the above general comments, the reader is referred to the molluscan shellfish rule (70 FR 48057 at 48062–48071). Because these comments do not raise issues specific to irradiated iceberg lettuce or spinach and because the agency has already responded to these comments in detail, they will not be addressed further here.

FDA also received two letters from PC and CFS that were submitted only to the docket for this rulemaking (Docket No. FDA–1999–F–2405 (formerly Docket No. 1999F–5522), FAP 9M4697). Many of the issues raised in these letters were also raised in comments submitted by PC and CFS to the docket for the agency rulemaking on irradiation of molluscan shellfish. Other issues raised in these letters were specific to the request in FAP 9M4697; these particular comments were not responded to in the molluscan shellfish rule. Below, the agency responds to the specific comments raised in these two letters from PC and CFS that were not addressed in the molluscan shellfish rule.

The agency also received an additional letter from Food and Water Watch (formerly PC) and CFS after the rule for the irradiation of molluscan shellfish published. The comments in this letter are also addressed below.

A. 2-Alkylcyclobutanones

During the evaluation of this petition and several others requesting various applications of irradiation, the agency received several comments on issues related to 2–ACBs. The agency has previously addressed most of these comments in the molluscan shellfish rule (70 FR 48057 at 48062–48071), and that discussion will not be repeated here. However, after the publication of the molluscan shellfish rule, the agency received an additional comment on 2–ACBs. This comment included a report that contained data on 2–ACBs present in irradiated turkey, hotdogs, and papayas.

As noted in section II. A of this document, 2–ACBs are formed in small quantities when fats are exposed to ionizing radiation. Of the three foods examined in the study submitted with the comment, only papayas are from the same generic class as iceberg lettuce and spinach. (Turkey and hotdogs are foods high in protein and fat that have little in common with leafy greens.) The report presents data indicating that 2–ACB concentrations in papaya flesh are indistinguishable from zero. There is no additional information in the paper other than concentrations of various alkylcyclobutanones in the three foods mentioned.

As previously noted in this document and in the molluscan shellfish rule, FDA has reviewed studies in which animals were fed diets containing irradiated foods of high fat content (meat, poultry, and fish). The agency concluded that no adverse effects were associated with the consumption of these high fat foods. Iceberg lettuce and spinach contain far less fat than meat, poultry, fish or molluscan shellfish. As previously noted in section II.B of this document, FDA has reviewed studies in which animals were fed diets containing irradiated fruits and vegetables. No adverse effects were associated with consumption of these food types. The comment provides no additional information that would alter the agency's conclusion that the consumption of irradiated iceberg lettuce and spinach does not present a health hazard.

B. List of Foods Covered by the Petition

One comment stated that ''FDA has no definitive list of foods that are covered by the petition,'' citing a personal communication of March 19, 2001. The comment goes on to state that ''[a] **Federal Register** filing of May 10, 2001, pertaining to the [above-referenced] petition establishes that the FDA [sic] no understanding as to which specific foods are covered by the petition.''

FDA disagrees with this comment. The **Federal Register** document of May 10, 2001, corrected an inadvertent exclusion of certain foods from the scope of the original filing notice. FDA also notes that a listing of each and every food covered by a food additive petition has never been required and is not necessary. The agency frequently evaluates food additive petitions intended to cover broad categories of food types. Further, this partial response authorizing irradiation of iceberg lettuce and spinach up to a maximum dose of 4.0 kGy addresses two specific foods, rendering the issue moot.

C. Toxicity Data

One comment states that the petition should be denied because ''[t]he petitioner submitted no toxicology data on any of the products that are ostensibly covered by the petition.''

FDA acknowledges that the petitioner did not submit new toxicological data specific to the foods in the petition. The petitioner made extensive reference to studies considered in earlier evaluations of the toxicological safety of irradiated foods by FDA, WHO, and others. As noted earlier, FDA has reviewed a large body of data relevant to the assessment of the potential toxicity of irradiated foods, including irradiated fruits and vegetables. There was no reason to submit additional copies of studies that had previously been reviewed by the agency.

One comment states that the petition should be denied ''because the validity of three of the studies referenced by the petitioner was questioned by the FDA's Irradiated Foods Task Group (IFTG) in 1982.'' The comment lists three studies, one of which ''was labeled 'reject' by the IFTG'' and two of which were ''labeled 'accept with reservation' by the IFTG.''

FDA does not disagree that the IFTG had questions regarding these three studies. FDA does not agree, however, that these 1982 findings by the IFTG provide a basis to deny the petition or the partial request that is the subject of this rulemaking. FDA has not relied on studies that were rejected by the IFTG in assessing the safety of irradiated iceberg lettuce and spinach or any other irradiated food. Some studies were accepted with reservation by the agency scientists on the IFTG because they did not meet modern standards in all respects; specifically, they may have used fewer animals, or examined fewer tissues than is common today. Nevertheless, these studies still provide important information that, when evaluated collectively, supports the conclusion that consumption of iceberg lettuce and spinach irradiated under the conditions proposed in this petition is safe. As noted earlier, FDA has reviewed a large body of data relevant to the assessment of the potential toxicity of irradiated fruits and vegetables, and to an assessment of the potential toxicity of irradiated iceberg lettuce and spinach specifically. The comment provides no basis to challenge FDA's conclusion that iceberg lettuce and spinach irradiated under the conditions set forth in the regulations in this document are safe.

Another comment stated that the petitioner claimed that a fourth study, conducted by Renner et al. (Ref. 61) ''provided [no] evidence of toxicity induced by irradiation.'' The comment took issue with the petitioner's characterization of this study, stating ''[t]he study found, however, 'significant' effects on DNA synthesis and 'significant loss of body weight' among rodents that ate irradiated food compared to that that ate non-irradiated food.''

The Renner et al. study consisted of six in vivo genetic toxicity tests that were carried out in several different animal species with irradiated or non-irradiated cooked chicken, dried dates, and cooked fish. FDA has previously evaluated the results of these tests and does not agree with comment's characterization of the study findings, which appear to be presented out of context.

In the Renner et al. study, the authors concluded that ''[n]one of the tests provided any evidence of genetic toxicity induced by irradiation.'' Further, the authors did not attribute a ''significant loss of body weight'' to consumption of irradiated food, but stated, rather, that ''[t]he nutritional effects of exposing Chinese hamsters for 7 days to a diet consisting entirely of dried dates were evidenced by a significant reduction in food intake and, consequently, a significant loss of body weight.'' The effect was observed in both animals fed non-irradiated dates and animals fed irradiated dates. The authors also reported various effects on DNA synthesis resulting from feeding Chinese hamsters diets consisting entirely of dried dates or cooked chicken, irradiated or not. Thus, the authors concluded that these effects were also not attributable to irradiation. Further, the authors state that ''In only one case in the nine tests described in this report and in two previous papers* * *was an effect seen that could be attributed to an irradiated foodstuff. This was with irradiated fish in the DNA metabolism test.'' The authors concluded that the specific

effect observed with irradiated fish in the DNA metabolism test was not an indication of genotoxic activity, but rather, that it ''* * *provided evidence for absence of genotoxic potential in fish so processed.'' The comment provides no basis to conclude that the studies and information reviewed by the agency and discussed previously in this document are not adequate to assess the safety of irradiated iceberg lettuce and spinach.

D. Hardy Pathogens

One comment submitted a copy of a newsletter published by the Food Safety Consortium. The comment stated that ''when irradiation is applied to meat in commercial plants, the pathogens present have evolved to survive the irradiation better, thus the irradiation does not achieve the levels of de-contamination that are predicted, and advertised, by the meat irradiation industry based on the lab studies.'' The article in the newsletter states that pathogens in a food processing plant are generally more resistant to stressful conditions than laboratory grown bacteria.

The comment provides no data that can be used in a safety assessment of irradiated food in general or irradiated iceberg lettuce and spinach, specifically. FDA also believes that the comment incorrectly characterizes the science behind the article in the newsletter. Scientists understand that bacteria grown under stressful conditions (e.g., high acidity, elevated temperatures) can manifest resistance to treatments that would be lethal to the same type of bacteria grown under less stressful conditions. Thus, any bacteria grown in nutrient-rich media under optimal conditions in the laboratory may be somewhat less resistant to any given treatment, including irradiation, than the same bacteria grown in nutrient-poor or other harsh conditions in a non-optimal environment.

FDA also notes that under the regulations set forth in § 179.25, radiation treatment of food must conform to a scheduled process, which is a written procedure to ensure that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions (including atmosphere and temperature) for the radiation to achieve its intended effect on a specific product and in a specific facility.[15] The regulations further require that the scheduled process be established by qualified persons having expert knowledge in radiation processing requirements of food and specific for that food and for the facility in which it is to be irradiated.

E. Effects on Organoleptic (Sensory) Properties

One comment argued that the petition should be denied because of ''organoleptic damage'' that raises ''serious concerns about the general wholesomeness of irradiated foods.''

The agency acknowledges that organoleptic changes can occur in irradiated foods. However, this comment provides no information that would establish a link between organoleptic changes in, and the safety of, irradiated foods. Consideration of organoleptic changes, in and of themselves, is beyond the scope of this rulemaking.

IV. Conclusions

Based on the data and studies submitted in the petition and other information in the agency's files, FDA concludes that the proposed use of irradiation to treat iceberg lettuce and spinach with absorbed doses that will not exceed 4.0 kGy is safe, and therefore, the regulations in § 179.26 should be amended as set forth below in this document. In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the use of irradiation on iceberg lettuce and spinach in a partial response to the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display at the Division of Dockets Management (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. References without asterisks are not on display; they are available as published articles and books.

*1. Diehl, J.F., ''Chemical Effects of Ionizing Radiation,'' pp. 43–88, in *Safety of Irradiated Foods*, 2d Ed., Marcel Dekker, Inc., New York, 1995.

2. Elias, P.S. and A.J. Cohen, *Recent Advances in Food Irradiation*, Elsevier Biomedical, Amsterdam, 1983.

*3. WHO, ''High-Dose Irradiation: Wholesomeness of Food Irradiated With Doses Above 10kGy,'' World Health Organization Technical Report Series, No. 890, Geneva, pp. 9–37, 1999.

4. Josephson, E.S. and M.S. Peterson, eds., *Preservation of Food by Ionizing Radiation*, vol. II, CRC Press, Boca Raton, FL, 1982.

5. Diehl, J.F., ''Radiolytic Effects in Foods,'' pp. 279–357, in *Preservation of Foods By Ionizing Radiation*, vol. I, E.S. Josephson and M.S. Peterson, eds., CRC Press, Boca Raton, FL,1982.

[15] Food irradiation processors are also subject to FDA's regulation requiring Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (CGMP) (21 CFR part 110) and other applicable regulations regarding proper food handling and storage conditions.

6. U.S. Department of Agriculture, Agricultural Research Service, USDA National Nutrient Database for Standard Reference, Release 20, Nutrient Data Laboratory Home Page, *http://www.ars.usda.gov/nutrientdata*, 2007.

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*8. Raffi, J., J.P. Agnel, C. Thiery, C. Frejaville, L. Saint-Lebe, ''Study of Gamma Irradiated Starches Derived form Different Foodstuffs: A Way for Extrapolating Wholesomeness Data,'' *Journal of Agricultural and Food Chemistry*, 29:1227–1232, 1981.

9. *Safety and Nutritional Adequacy of Irradiated Food*, World Health Organization, Geneva, 1994.

*10. Memorandum for FAP 9M4697 from K. Morehouse, FDA, to L. Highbarger, FDA, dated August 10, 2001.

*11. Raffi, J. and J.P. Agnel, ''Influence of Physical Structure of Irradiated Starches on their ESR Spectra Kinetics,'' *Journal of Physical Chemistry*, 87:2369–2373, 1983.

*12. Thiery, J.M., J.P. Theiry, P. Angel, P. Vincent, C. Battesti, J. Raffi, and J.C. Evans, ''Electron Spin Resonance Study of Spin-Trapped Radicals from Gamma Irradiation of Glucose Oligomers,'' *Magnetic Resonance In Chemistry*, 28:594–600, 1990.

*13. Merritt, C. and I.A. Taub, ''Commonality and Predictability of Radiolytic Products in Irradiated Meats,'' pp. 27–58, in *Recent Advances in Food Irradiation*, P.S. Elias and A.J. Cohen, eds., Elsevier Biomedical, Amsterdam, 1983.

*14. Nawar, W.W., ''Volatiles from Food Irradiation,'' *Food Reviews International*, 2:45–78, 1986.

*15. Nawar, W.W., ''Comparison of Chemical Consequences of Heat and Irradiation Treatment of Lipids,'' pp. 115–127, in *Recent Advances in Food Irradiation*, P. S. Elias and A. J. Cohen, eds., Elsevier Biomedical, Amsterdam, 1983.

*16. Crone, A.V.J., J.T.G. Hamilton, and M.H. Stevenson, ''Effect of Storage and Cooking on the Dose Response of 2-Dodecylcyclobutanone, a Potential Marker for Irradiated Chicken,'' *Journal of the Science of Food and Agriculture*, 58:249–252, 1992.

*17. Gadgil, P., K.A. Hachmeister, J.S. Smith, and D.H. Kropf, ''2-Alkylcyclobutanones as Irradiation Dose Indicators in Irradiated Ground Beef Patties,'' *Journal of Agriculture and Food Chemistry*, 50:5746–5750, 2002.

*18. Seibersdorf Project Report, International Programme on Irradiation of Fruit and Fruit Juices, Chemistry and Isotopes Department, National Centre for Nuclear Energy, Madrid, Spain, vol.8, 1966.

*19. Memorandum for FAP 9M4697 from K. Morehouse, FDA, to L. Highbarger, FDA, dated February 20, 2008.

*20. Locas, C., and V.A. Yaylayan, ''Origin and Mechanistic Pathways of Formation of the Parent Furan-a Toxicant,'' *Journal of Agricultural and Food Chemistry*, 52:6830–6836, 2005.

*21. Fan, X., and K.J.B. Sokorai, ''Effect of Ionizing Radiation on Furan Formation in Fresh-Cut Fruits and Vegetables,'' *Journal of Food Science*. 73(2): C79–C83, 2008.

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List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and record keeping requirements, Signs and symbols.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

■ 1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

■ 2. Section 179.26 is amended in the table in paragraph (b) by adding a new item ''12.'' under the headings ''Use'' and ''Limitations'' to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * * * * * *	
12. For control of food-borne pathogens and extension of shelf-life in fresh iceberg lettuce and fresh spinach.	Not to exceed 4.0 kGy.

* * * * *

Dated: August 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19573 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314, 601, and 814

[Docket No. FDA–2008–N–0032] (formerly Docket No. 2008N–0021)

RIN 0910–ZA32

Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding changes to an approved new drug application (NDA), biologics license application (BLA), or medical device premarket approval application (PMA). This final rule provides that a supplemental application submitted under certain FDA regulations is appropriate to amend the labeling for an approved product to reflect newly acquired information and to add or strengthen a contraindication, warning, precaution, or adverse reaction if there is sufficient evidence of a causal association with the drug, biologic, or device, as defined in other FDA regulations and guidance documents.

DATES: This rule is effective September 22, 2008.

FOR FURTHER INFORMATION CONTACT:

For information regarding devices: Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010.

For information regarding biologics: Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, Rockville MD 20852, 301–827–0373.

For information regarding drugs: Laurie Burke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6462, Silver Spring, MD 20933, 301–796–0900.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 16, 2008 (73 FR 2848), FDA proposed amending its regulations regarding changes to an NDA, BLA, or PMA to codify the agency's longstanding view concerning when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency's review and approval of such change (the January 2008 proposed rule). With respect to drugs, § 314.70(c)(6)(iii) (21 CFR 314.70(c)(6)(iii)) provides that certain labeling changes related to an approved drug may be implemented upon receipt by the agency of a supplemental new drug application (sNDA) that includes the change. The corresponding regulation for biological products, § 601.12(f)(2) (21 CFR 601.12(f)(2)), provides that products with certain labeling changes may be distributed before FDA approval. Similarly, with respect to devices, § 814.39(d) (21 CFR 814.39(d)) provides that certain labeling changes may be placed into effect upon submission of a PMA supplement, but prior to the sponsor's receipt of a written FDA order approving the supplement. The supplements described by §§ 314.70(c), 601.12(f)(2), and 814.39(d) are commonly referred to as ''changes being effected supplements''

or ''CBE supplements.''[1] FDA proposed amending these provisions to affirm that a CBE supplement is appropriate to amend the labeling for an approved product only to reflect newly acquired information and to make it clear that a CBE supplement may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug, biologic, or medical device. The phrase ''sufficient evidence of a causal association'' refers to the standards for drugs and biologics described in § 201.57(c)(6) (21 CFR 201.57(c)(6)) (for Warnings and Precautions—''reasonable evidence''), and in § 201.57(c)(7) (21 CFR 201.57(c)(7)) (for Adverse Reactions—''some basis to believe'') and to the standard for devices in the Device Labeling Guidance, General Program Memorandum G91–1 (March 8, 1991) (*http://www.fda.gov/cdrh/g91-1.html*) (''reasonable evidence'') for the level of evidence needed to support a causal association with these medical products.

As described in the January 2008 proposed rule, FDA believes that amending FDA's CBE regulations is consistent with the agency's role in protecting the public health. Before approving an NDA, BLA, or PMA, FDA undertakes a detailed review of the proposed labeling, allowing only information for which there is a scientific basis to be included in the FDA-approved labeling. Under the Federal Food, Drug, and Cosmetic Act (the act), the Public Health Service Act (the PHS Act), and FDA regulations, the agency makes approval decisions, including the approval of supplemental applications, based on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling. See, e.g., 21 U.S.C. 355(d); 42 U.S.C. 262; 21 U.S.C. 360e(d)(2). FDA's comprehensive scientific evaluation is embodied in the labeling for the product which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. Expressly requiring that a CBE supplement reflect newly acquired information and be based on sufficient evidence of a causal association will help to ensure that scientifically accurate information appears in the approved labeling for such products.

II. Changes to the January 2008 Proposed Rule

FDA has made the following changes to the January 2008 proposed rule:

The definition of ''newly acquired information'' has been revised to clarify that data, whether derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) needs to be of a ''different type or greater severity or frequency than previously included in submissions to FDA''. The codified section of the January 2008 proposed rule suggested that this limitation applied only to data derived from reports of adverse events. Instead, it applies to data derived from new clinical studies, reports of adverse events, and new analyses of previously submitted data.

In addition, FDA has made one technical correction to the January 2008 proposed rule. The technical correction is in § 601.12, where an amendment was proposed adding paragraph (f)(5), containing the definition of ''newly acquired information.'' In fact, the amendment should have proposed adding this definition to paragraph (f)(6) of § 601.12 rather than to paragraph (f)(5) of § 601.12.

III. Comments

FDA received approximately 20 comments to the January 2008 proposed rule. The comments were submitted by consumer advocacy groups, individuals, law firms, law professors, pharmaceutical companies, trade associations, and Members of Congress.

(Comment 1) Several comments stated that this proposed amendment would make it more difficult for sponsors to warn about new risks. Most of these comments were focused on the aspect of the rule that imposed a requirement that sponsors have a sufficient amount of causal evidence before a CBE should be used.

In addition, comments argued that FDA should distinguish between situations when sponsors are obligated to warn of a new risk, and situations when the sponsor is permitted to warn. For example, some comments stated that the requirement in § 201.57(c)(6) that there be some evidence of a causal relationship should apply to situations when a manufacturer must warn, but should not apply to when manufacturers may warn. These comments argue that public policy should not discourage sponsors from warning, even when the regulations do not require it.

Similarly, one comment argued that causation is not a binary issue (i.e., causation is either present or not). Rather, the causal relationship between a product and an adverse effect is often difficult to establish and may require large trials, often specifically designed to assess the risk. One comment argued that because of this difficulty, drug and device sponsors may delay warning and delay making labeling changes by asserting that the CBE regulation (if finalized as proposed) would not permit them to amend their labeling.

FDA does not agree that this rule will make it more difficult to provide appropriate warnings regarding hazards associated with medical products. This rule is intended to describe FDA's existing labeling standards and policies, but does not amend the standards under which sponsors must provide warnings regarding risks (§ 201.57(c)(6)). Nor is the rule intended to suggest that there is a mathematically precise distinction between whether there is, or is not, sufficient evidence of a causal relation between a drug and an adverse effect to support its inclusion in the labeling. The rule is, nevertheless, sufficiently clear and objective to allow sponsors to determine whether a medical product's labeling should be amended. If new safety information meets the requirements of § 201.57(c)(6), it is appropriate for inclusion in the labeling of a drug or biologic and a sponsor must update its labeling ''as soon as'' such information becomes available. That section states that causation need not have been ''definitely established'' for a warning to be required to appear in labeling, but rather that there need only be ''reasonable'' evidence of a causal association with the drug, a standard that could be met by a wide range of evidence. A CBE submission may be made when the evidence meets the standard set forth in this rule, even if that evidence would not also support a higher evidentiary standard, such as a finding that there is a ''preponderance'' of evidence that a product actually causes a particular kind of adverse event. A sponsor's submission or FDA's acceptance of a CBE supplement does not necessarily mean that a drug product actually has caused any particular adverse event or type of adverse event.

Through § 201.57 (and the predecessor regulation, now codified at § 201.80 (21 CFR 201.80)), the agency set uniform standards for drug labeling, seeking to ensure that scientifically sound information is provided in the labeling of the drug. There is no reason the standard for adding new information to labeling should be different from the

[1] For devices, such supplements are also referred to as Special PMA Supplements. This document will use the term ''CBE supplement.''

standard for the initial labeling. If new information about a drug comes to light, a sponsor must make a decision as to whether the requirements of § 201.57 are met, and whether to submit a CBE supplement or other type of supplemental application. Failure to update labeling as required could result in regulatory actions or criminal penalties. If there is doubt as to whether the standard of § 201.57(c)(6) has been met, a sponsor should confer with FDA. The agency has clarified by regulation and guidance the types of supplements that should be filed to satisfy a sponsor's obligations to change a drug's labeling, and sponsors can consult with FDA on that question as well. *See* 21 CFR 314.70; Guidance for Industry: Changes to an Approved NDA or ANDA (November 1999) (*http://www.fda.gov/cder/guidance/2766fnl.pdf*).

This rule does not undermine a sponsor's responsibility to maintain its label—rather, it clarifies FDA's longstanding practice of requiring that sponsors must have sufficient evidence that the standards are met (§ 201.57(c) and Device Labeling Guidance).

With respect to comments suggesting that § 201.57 sets the standard for when sponsors must warn, but that a lower standard should be used under § 314.70(c)(6) for when a sponsor may warn, FDA has previously stated and reiterates here that it ''interprets the Act to establish both a 'floor' and a 'ceiling', such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading'' (71 FR 3922 at 3935, January 24, 2006) (the 2006 Physician Labeling Rule). FDA, therefore, declines to set different standards for when a sponsor must warn, as opposed to when it may warn of a particular risk or adverse event.

(Comment 2) Several comments stated that the rule would conflict with the intent of Congress. FDA in no way believes that this rule conflicts with Congressional intent. Another, comment stated that Congress did not intend for the act to preempt State law because there is no express preemption provision with respect to drugs. Several comments referred to the recently enacted Food and Drug Administration Amendments Act of 2007 (FDAAA) in support of this position. These comments suggest that for FDA to change the circumstances when sponsors could update their labeling by a CBE would conflict with congressional intent. FDAAA provided additional authority for FDA to require sponsors to make safety related changes to their labeling. The statute also included a rule of construction as part of a paragraph providing new authority to the Secretary to require labeling changes for drug products: ''This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).'' (Section 505(o)(4)(I) of the act (21 U.S.C. 355(o)(4)(I))).

FDA does not believe that the absence of an express preemption provision with respect to drugs affects the application of the doctrine of implied preemption. Furthermore, FDA does not agree that the rule of construction affects FDA's ability to finalize the January 2008 proposed rule for several, independent reasons.[2] The January 2008 proposed regulation is consistent with the rule of construction. First, the rule of construction, by its terms, contemplates amendments to applicable regulations by its reference to ''successor regulations'' governing a sponsor's obligation to change product labeling. Congress, therefore, expressly acknowledged that FDA's regulations are not static and may be subsequently amended by the agency, as FDA is doing here. Second, the rule of construction operates to preserve Federal labeling obligations only in the face of an argument that ''this paragraph''—21 U.S.C. 355(o)(4), the new statutory provision permitting the Secretary of Health and Human Services (the Secretary) to impose labeling changes after meeting certain procedural requirements—''affects'' those responsibilities. Third, the rule of construction refers to, and therefore preserves only a sponsor's Federal-law (as opposed to State-law) ''responsibility[ies] * * * to maintain its label.'' As was noted in the U.S. Government's amicus brief at the merits stage in *Wyeth* v. *Levine*, No. 06–1249 (June 2008) (*http://www.justice.gov/osg/briefs/2007/3mer/1ami/2006-1249.mer.ami.pdf*), the rule of construction ''simply means that the relevant amendments do not affect obligations under other *federal* laws. It does not manifest any intent to depart from the application of ordinary principles governing the preemption of conflicting *state* laws. * * * [T]he text of the rule of construction that Congress actually enacted, which is limited to the effect of Section 901, itself preserves *complementary federal* requirements without evincing any intent to protect *conflicting state* laws.'' *Id.* at 32 (emphases in original).

(FDA has verified the Web site addresses in this document, but FDA is not responsible for subsequent changes after this document publishes in the **Federal Register**).

In other words, the rule of construction makes it clear that a sponsor cannot contend that, because the Secretary has the power to order new labeling changes, the sponsor no longer has an obligation to monitor post-marketing experiences and maintain its labeling under applicable Federal regulations. Indeed, it can maintain its labeling by using all existing tools, including through prior approval supplements, CBE-30 day supplements (§§ 314.70(c), 601.12(c) and 814.39(e)), and CBE supplements, along with other changes that may be reported in an annual report. Under both the rule of construction and this final rule, a sponsor still must update its labeling under Federal law ''to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug'' (§ 201.57(c)(6)), and add other risk information as required by the regulations (§ 201.57(c)).

If FDA were to interpret section 505(o)(4) of the act as eliminating the ability or obligation under Federal law of a sponsor to ''maintain'' its label, this would conflict with the rule of construction. But this final rule does not take away a sponsor's obligation to maintain its labeling under Federal law under appropriate circumstances. FDA is amending the text of the rules at issue here not because of the new powers in section 505(o)(4) of the act, but to clarify a sponsor's responsibilities and to make the text of the regulations match FDA's practice regarding CBE labeling changes, which predate FDAAA. Manufacturers continue to have a responsibility under Federal law, including the amended regulations under this rulemaking, to maintain their labeling and update the labeling with new safety information.

(Comment 3) One comment asserted that this rule could undermine consumer confidence in medical products and FDA. Consumer confidence in medical products and in FDA itself is critically important. This amendment is intended to clarify FDA's existing policies and is intended to ensure that scientifically valid and appropriately worded warnings will be provided in the approved labeling for medical products, and to prevent overwarning, which may deter

[2] FDA notes that the rule of construction in 21 U.S.C. 355(o)(4) on its face does not relate to medical devices.

appropriate use of medical products, or overshadow more important warnings. Accordingly, FDA does not agree that the rule will undermine confidence in medical products or the agency.

(Comment 4) One comment stated that the January 2008 proposed rule's reference to ''newly acquired information'' might undermine warnings in situations where a sponsor warns about a particular risk, but then later information demonstrates that the warning was insufficient.

FDA believes that the final rule addresses this concern. First, if later data or analyses demonstrate that prior warnings were insufficient, such data would clearly qualify as newly acquired information under the rule. Indeed, the rule expressly provides that new analyses of previously submitted information are considered new information that could be submitted by a CBE supplement (provided that other requirements for a CBE supplement are met). Therefore, if a sponsor determined that existing warnings were insufficient based on newly acquired information such as a new analysis of previously submitted data, the sponsor could still submit a CBE based on its new analysis of the previous data, provided the other requirements of the rule are met. Moreover, FDA now has new tools to address this situation, including its authority to require labeling changes under section 505(o) of the act.

(Comment 5) Several comments asserted that sponsors, not FDA, have the most information about their products and should have authority to revise their labeling as soon as new information comes to light.

Sponsors are still required to act promptly to add risk information to labeling (§ 201.57(c)(6)). This rule describes the standard for one type of change to the labeling. It is intended to clarify the circumstances in which sponsors are required to update labeling, not to undermine or remove a sponsor's obligation to modify labeling to reflect appropriate new information. Under FDA's regulations and this final rule, sponsors are required to warn as soon as appropriate new information comes to light (§ 201.57(c)(6)).

(Comment 6) Several comments stated that FDA did not have sufficient resources to review all potential warnings before labeling may be updated. As stated in the January 2008 proposed rule, FDA does not consider this amendment to substantively change the standards for submission of CBE or prior review supplements. The agency does not expect that it will increase the number of prior approval supplements or otherwise increase agency workloads.

(Comment 7) One comment requested that FDA clarify the relationship between the January 2008 proposed rule and statements made by FDA in the preamble to the 2006 Physician Labeling Rule (71 FR 3922). The comment inquired whether these changes ''supersede'' certain statements in the preamble to the 2006 Physician Labeling Rule. The agency believes that these amendments are consistent with prior statements by FDA, including those in the 2006 Physician Labeling Rule. The preamble to the 2006 Physician Labeling Rule set forth a number of principles regarding FDA's regulation of drug labeling. See, e.g. 71 FR 3922 at 3935 (''FDA interprets the act to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act'' * * *); ibid. (''State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products * * *''). That preamble also set forth some non-exclusive examples of instances of preemption. Id. at 3935–3936 (stating that ''at least'' the enumerated cases are preempted). In a proposed rule that published in the **Federal Register** of May 29, 2008 (73 FR 30831 at 30861), FDA reiterated its support for the general principles underlying preemption set forth in the 2006 Physician Labeling Rule. In briefs recently filed in the Supreme Court of the United States and in testimony before Congress, FDA has also stated a more generally applicable rule that is consistent with the examples of preempted cases and the principles set forth in the preamble to the 2006 Physician Labeling Rule that: (1) The labeling requirements are not a mere minimum safety standard, but rather strike a balance between risks and benefits, and (2) FDA's regulations permit changes in labeling without prior approval only in narrow circumstances. Specifically, FDA has explained that State law claims that ''challenge labeling that FDA approved after being informed of the relevant risk'' are preempted. Brief of the United States as Amicus Curiae Supporting Petitioner, *Wyeth* v. *Levine*, No. 06–1249; Testimony of Deputy FDA Commissioner Randall Lutter before The House Committee on Oversight and Government Reform 5 (2008) *http://oversight.house.gov/documents/20080514142253.pdf* (''* * * State law claims are preempted if they challenge a design or labeling that FDA approved, after being informed of the relevant health risk * * *''). FDA reiterates and reaffirms here the positions set forth in those documents. FDA further notes that FDA there explained the interplay between this CBE regulation and preemption. FDA believes that this explanation sufficiently describes the relationship between this CBE regulation and the 2006 Physician Labeling Rule preamble.

(Comment 8) One comment requested that FDA make it clear that information previously known to the manufacturer, but not submitted to FDA, can be eligible for inclusion in a CBE amendment.

The term ''newly acquired information'' is defined in the final rule as ''information not previously submitted to FDA * * *.'' Accordingly, if information was previously known to the manufacturer, but not submitted to FDA, it would be ''newly acquired information'' that may qualify for inclusion in a CBE supplement (provided other requirements for a CBE supplement have been met).

(Comment 9) Several comments requested that FDA clarify the effect of this amendment on State tort liability and preemption, and one comment stated that this rule lacked a sufficient statement of irreconcilable conflict to justify the agency's assertion of implied preemption of ''all [S]tate law''. This rule does not preempt all State tort law and, furthermore, an ''irreconcilable conflict'' (i.e., an impossibility of compliance with both Federal and State law) is not the only basis for preemption of State law. Under implied preemption principles, if a State law frustrates Federal objectives, the State law is preempted. As a result, FDA's views on preemption, as explained elsewhere in this preamble, are amply justified by well-established principles of preemption. See *Geier* v. *American Honda Co.*, 529 U.S. 861 (2000); *English* v. *General Electric Co.*, 496 U.S. 72, 79 (1990); *Florida Lime & Avocado Growers, Inc.*, 373 U.S. 132, 142–43 (1963); *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). Moreover, liability imposed under State tort law constitutes a State ''requirement'' within the meaning of 21 U.S.C. 360k(a). See *Reigel* v. *Medtronic*, 128 S.Ct. 999, 1008–09 (2008). For further discussion of the scope of preemption, see the response to comment 7 of this document and section VIII. Federalism of this document.

(Comment 10) One comment requested that FDA develop an alternative mechanism to address proposed labeling changes. FDA believes that its regulations (as modified

in this final rule) provide appropriate and adequate regulatory pathways for updating and modifying labeling of drugs, biological products, and medical devices. See § 314.70(c) (for drugs), § 601.12(f)(2) (for biological products) and § 814.39(d) (for medical devices).

(Comment 11) One comment requested that FDA clarify the degree of certainty that is required for demonstrating causation under FDA's regulations. FDA does not believe that additional clarification of its labeling rules is necessary. The regulations set forth in § 201.57 provide relevant standards for when information is appropriate for inclusion in labeling, including causation standards. FDA believes that standard is sufficiently clear and objective.

(Comment 12) One comment noted that the preamble to the January 2008 proposed rule stated that ''FDA intends to consider information 'newly acquired' if it consists of data, analyses, or other information not previously submitted to the agency, *or submitted within a reasonable time period prior to the CBE supplement* * * *.'' (73 FR 2848 at 2850) (emphasis added). The comment requested that FDA clarify the temporal relationship between the submission of new information to FDA and a subsequent CBE supplement. FDA agrees that this issue should be clarified here so as to provide greater guidance to sponsors in determining their regulatory obligations. Newly acquired information includes information not previously submitted to FDA. If a sponsor submits data or analysis to FDA as part of a discussion of the kind of labeling change that would be appropriate and decides as a result of that discussion to prepare and submit a CBE supplement, then the supporting data or analysis will not be considered ''previously submitted to FDA''—even if it was not first submitted on the same day as the CBE supplement. This allows for a labeling change when a sponsor submits data or analysis to FDA before the sponsor has completed its CBE supplement, and is also designed so as not to deter the sponsor from submitting the information for fear that such a submission would preclude the sponsor from making a CBE change. This clarification is designed to address the situation where a sponsor submits data or analyses to FDA as part of the process of determining what labeling change is appropriate, and then diligently and promptly prepares a CBE supplement.

Moreover, FDA also notes that the definition of ''newly acquired information'' includes ''new analyses'' of previously submitted information. If a sponsor submits information to FDA, then later conducts a new analysis that demonstrates that labeling should be revised to account for that information, a CBE would be appropriate. For example, if the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for ''newly acquired information''.

(Comment 13) One comment requested that FDA clarify the relationship between the CBE regulations and risk evaluation and mitigation strategies (REMS) for drugs and biological products.

Under the new authority provided in FDAAA, FDA may require the submission of a proposed REMS if FDA believes that such a strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS must be approved by FDA (21 U.S.C. 355–1(h)), as must proposed modifications to a REMS (21 U.S.C. 355–1(g)). Accordingly, if the labeling for a drug describes an element of an approved REMS, the sponsor must receive prior approval of any labeling changes that would necessitate a change to the sponsor's REMS. For example, if a REMS included elements to assure safe use under section 505–1(f) of the act, some of those elements might be described in the approved labeling for the drug or biologic. If the sponsor became aware of newly acquired safety information that would otherwise be appropriate for a CBE, but would require the sponsor to modify an element to assure safe use that is required under a REMS, the sponsor would need to receive prior approval of the labeling change. However, if the newly acquired information is related to the concern leading to a REMS but the proposed change to labeling could be made without requiring a modification of the REMS, the approved labeling for the product could be strengthened without prior approval. For example, if a REMS was imposed requiring periodic monitoring of liver enzymes to ensure the risk of liver toxicity for a drug was outweighed by the benefits of the drug, strengthening warnings related to that risk may be made by a CBE supplement (provided that other requirements for a CBE supplement are met and that the change can be made without modifying the REMS).

(Comment 14) One comment requested that FDA clarify that any change to the Highlights section of the labeling of a drug or biologic must be made by a prior approval supplement.

The agency agrees that this issue should be clarified, but does not agree that changes to Highlights can never be accomplished by a CBE supplement. Under existing regulations, changes to the Highlights are classified as a ''major change,'' requiring a prior approval supplement (§ 314.70(b)(2)(v)(C)). Accordingly, in most cases, changes to Highlights will require a prior approval supplement. However, in the preamble to the January 2008 proposed rule, we noted that FDA could waive this limitation under § 314.90 or request that a sponsor make a change to Highlights under § 314.70(c)(6)(iii)(E) or § 601.12(f)(2)(E). These provisions authorize FDA to waive the Highlights limitation or otherwise ask the sponsor to submit a CBE supplement in appropriate circumstances.

(Comment 15) One comment requested that FDA clarify that sponsors may not use the CBE process to submit labeling changes for drugs or biological products under section 505(o) of the act.

FDA disagrees with this comment. Under section 505(o) of the act, FDA must notify the sponsor if the agency becomes aware of new safety information that should be included in the labeling for a particular drug or biologic. Following that notification, the sponsor must submit a ''supplement'' proposing changes to the labeling or submit a statement explaining the reasons why the sponsor believes the labeling change is not warranted. Nothing in section 505(o) limits this ''supplement'' to a prior approval supplement. In fact, to effect the change most rapidly, FDA may request that the sponsor file a CBE supplement under these circumstances.

(Comment 16) One comment requested that FDA provide a comprehensive, written response to every CBE supplement submitted to the agency by a sponsor, describing FDA's grounds for approval, disapproval, or, as the case may be, request for modification to the submitted CBE supplement. FDA disagrees with this comment. The comment failed to provide a compelling justification for this proposal.

(Comment 17) One comment asserted that if FDA finalizes this rule, it will create a disincentive for sponsors to conduct additional trials of their products because the sponsors would have to provide additional warnings if causation is shown. Under current regulations, sponsors must warn about risks of approved products if the requirements for updating labeling are triggered. This rule does not change those standards. FDA therefore does not believe that it will change the incentives

for sponsors to conduct new clinical trials.

(Comment 18) One comment stated that the rule would unjustifiably impose an added regulatory burden. FDA disagrees with this comment, as this rule does not add to the existing regulatory burden. Rather, as previously stated, the rule simply affirms that a CBE supplement is appropriate to amend the labeling for an approved product only to reflect newly acquired information and makes it clear that a CBE supplement may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug, biologic, or medical device. For further discussion of the regulatory burden, see sections V. Analysis of Impacts and VI. Paperwork Reduction Act of this document.

IV. Legal Authority

As explained in the January 2008 proposed rule, FDA's legal authority to modify §§ 314.70, 601.12, and 814.39 arises from the same authority under which FDA initially issued these regulations. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and the Public Health Service Act (42 U.S.C. 201 *et seq.*) provide FDA with authority over the labeling for drugs, biological products, and medical devices, and authorize the agency to enact regulations to facilitate FDA's review and approval of applications regarding the labeling for such products.

Section 502 of the act (21 U.S.C. 352) provides that a drug, biologic,[3] or medical device will be considered misbranded if, among other things, the labeling for the product is false or misleading in any particular (21 U.S.C. 352(a)). Under section 502(f) of the act, a product is misbranded unless its labeling bears adequate directions for use, including adequate warnings against, among other things, unsafe dosage or methods or duration of administration or application. Moreover, under section 502(j) of the act, a product is misbranded if it is dangerous to health when used in the manner prescribed, recommended, or suggested in its labeling.

In addition to the misbranding provisions, the premarket approval provisions of the act authorize FDA to require that product labeling provide adequate information to permit safe and effective use of the product. Under section 505 of the act (21 U.S.C. 355), FDA will approve an NDA only if the drug is shown to be both safe and effective for its intended use under the conditions set forth in the drug's labeling. Similarly, under section 515(d)(2) of the act (21 U.S.C. 360e(d)(2)), FDA must assess whether to approve a PMA according to the ''conditions of use prescribed, recommended, or suggested in the proposed labeling'' of the device. Section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to issue regulations for the efficient enforcement of the act.

Section 351 of the PHS Act (42 U.S.C. 262) provides additional legal authority for the agency to regulate the labeling of biological products. Licenses for biological products are to be issued only upon a showing that the biological product is safe, pure, and potent (42 U.S.C. 262(a)). Section 351(b) of the PHS Act (42 U.S.C. 262(b)) prohibits any person from falsely labeling any package or container of a biological product. FDA's regulations in part 201 apply to all prescription drug products, including biological products.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because these amendments to existing regulations are intended only to codify the agency's interpretation of current policy, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The objective of the final rule is to make explicit the agency's view of when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency's review of the change. More specifically, the purpose of the final rule is to clarify that a CBE supplement is appropriate to amend the labeling for an approved product only to reflect newly acquired information, and to clarify that a CBE supplement may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is reasonable evidence of a causal association with the approved drug, biologic, or medical device. FDA does not consider this to be a substantive policy change, and it does not alter the agency's current practices with respect to accepting or rejecting labeling changes proposed by a CBE supplement.

Because this final rule does not establish any new regulatory or recordkeeping requirements, the agency does not expect that there will be any associated compliance costs. The final rule simply clarifies the agency's interpretation of when sponsors are allowed to add information regarding the risks associated with a product to the labeling without prior approval from FDA. It is expected that these clarifications will promote more effective and safe use of approved drug, biologic, and medical device products. The agency believes that any potential impacts of these amendments to existing regulations will be minimal because this action does not represent a substantive change from current policy. We did not receive any comments on the January 2008 proposed rule that would cause us to reconsider these determinations.

VI. Paperwork Reduction Act of 1995

This final rule refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 35013520). The collections of information in 21 CFR part 314 have been approved under OMB Control No. 0910–0001 (expires May 31, 2011); 21 CFR part 601 have been approved under OMB Control No. 0910–0338 (expires June 30, 2010); and 21 CFR part 814 have been approved under OMB Control No. 0910–0231 (expires November 30, 2010). Therefore,

[3] Although the language of section 502 of the act refers only to drugs and devices, it is also applicable to biologics. (See 42 U.S.C. 262(j)).

clearance by OMB under the PRA is not required.

VII. Environmental Impact

The agency has determined under 21 CFR 25.31(a) and 25.34(e) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Like any Federal requirement, if a State law requirement makes compliance with both Federal law and State law impossible, or would frustrate Federal objectives, the State requirement would be preempted. See *Geier* v. *American Honda Co.*, 529 U.S. 861 (2000); *English* v. *General Electric Co.*, 496 U.S. 72, 79 (1990); *Florida Lime & Avocado Growers, Inc.*, 373 U.S. 132, 142–43 (1963); *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). Moreover, if a State requirement constitutes a requirement that is different from, or in addition to, a Federal requirement applicable to a medical device, and which relates to the safety or effectiveness of the device, the State law requirement is preempted. See 21 U.S.C. 360k(a), *Reigel* v. *Medtronic*, 128 S.Ct. 999 (2008). In addition to the discussion above in response to comment 7 of this document, FDA notes that, at least when a sponsor did not meet the standard to change its labeling through a CBE supplement under this rule to include the warning a plaintiff alleges should have been added to labeling, State law liability that is premised on a failure to warn is preempted.

FDA has provided the States with an opportunity to comment on the January 2008 proposed rule. Specifically, following publication of the January 2008 proposed rule in the **Federal Register**, FDA issued a ''Dear Colleague'' letter on January 17, 2008. The purpose of this letter was to alert officials in various organizations within the 50 States about the rulemaking, including officials with State pharmacy boards, State medical boards, health commissioners, and drug program directors. The letter briefly explained what the rulemaking would do when it became final and it encouraged the officials to review the January 2008 proposed rule and provide FDA with any comments they may have concerning the impact this rule may have on the following: (1) On the States, (2) on the relationship between the national government and the States, or (3) on the distribution of power and responsibilities among the various levels of government. FDA received one comment that appears to be in response to this ''Dear Colleague'' letter. This comment is addressed in the final rule.

List of Subjects

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 314, 601, and 814 are amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 2. Section 314.3 is amended in paragraph (b) by alphabetically adding the definition for ''newly acquired information'' to read as follows:

§ 314.3 Definitions.

* * * * *

(b) * * *

Newly acquired information means data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

* * * * *

■ 3. Section 314.70 is amended by revising paragraphs (c)(6)(iii) introductory text and (c)(6)(iii)(A) to read as follows:

§ 314.70 Supplements and other changes to an approved application.

* * * * *

(c) * * *

(6) * * *

(iii) Changes in the labeling to reflect newly acquired information, except for changes to the information required in § 201.57(a) of this chapter (which must be made under paragraph (b)(2)(v)(C) of this section), to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter;

* * * * *

PART 601—LICENSING

■ 4. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 5. Section 601.12 is amended by revising paragraphs (f)(2)(i) introductory text and (f)(2)(i)(A), and by adding paragraph (f)(6) to read as follows:

§ 601.12 Changes to an approved application.

* * * * *

(f) * * *

(2) *Labeling changes requiring supplement submission—product with a labeling change that may be distributed before FDA approval.* (i) An applicant shall submit, at the time such change is made, a supplement for any change in the package insert, package label, or container label to reflect newly acquired information, except for changes to the package insert required in § 201.57(a) of this chapter (which must be made under paragraph (f)(1) of this section), to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter;

* * * * *

(6) For purposes of paragraph (f)(2) of this section, information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 6. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 7. Section 814.3 is amended by adding paragraph (o) to read as follows:

§ 814.3 Definitions.

* * * * *

(o) *Newly acquired information* means data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

■ 8. Section 814.39 is amended by revising paragraphs (d)(1) introductory text and (d)(2)(i) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under § 814.17 of a written FDA order approving the PMA supplement provided that:

* * * * *

(2) * * *

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association.

* * * * *

Dated: August 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19572 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2008–0424]

Special Local Regulation; U.S. Nationals Waterski Racing Championship; Mission Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the U.S. Nationals Waterski Racing Championship special local regulation on Mission Bay from 8 a.m. on October 10, 2008 through 5 p.m. on October 12, 2008. This action is necessary to provide for the safety of the participants, crew, spectators, participating vessels, and other vessels and users of the waterway. During the enforcement period, no person or vessel may enter the special local regulation without permission of the Captain of the Port.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 8 a.m. on October 10, 2008 through 5 p.m. on October 12, 2008.

FOR FURTHER INFORMATION CONTACT: Petty Officer Kristen Beer, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at (619) 278–7233.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation for the U.S. Nationals Waterski Racing Championship in 33 CFR 100.1101 on October 10, 2008, from 8 a.m. to 7 p.m., October 11, 2008, from 8 a.m. to 7 p.m., and October 12, 2008, from 8 a.m. to 7 p.m.

Under the provisions of 33 CFR 100.1101, a vessel may not enter the regulated area, unless it receives permission from the COTP. Spectator vessels may safely transit outside the regulated area but may not anchor, block, loiter in, or impede the transit of participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 100.1101(a) and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, local radio stations and area newspapers. If the COTP or his designated representative determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: August 8, 2008.

T.H. Farris,

Captain, U.S. Coast Guard, Captain of the Port Sector San Diego.

[FR Doc. E8–19532 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2008–0769]

Oregon Symphony Celebration Fireworks Display, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the ''Oregon Symphony Celebration Fireworks Display safety zone on the Willamette River''; from 8:30 p.m. through 11:30 p.m. on August 28, 2008. This action is necessary to provide a safe display for the public and to keep them clear of the fall out area of the fireworks. During the enforcement period, no person or vessel may enter the safety zone without permission of the Captain of the Port Portland or his designated representative.

DATES: The regulations in 33 CFR 165.1315(a)(7) will be enforced from 8:30 p.m. through 11:30 p.m. on August 28, 2008.

FOR FURTHER INFORMATION CONTACT: BM2 Joshua Lehner, Sector Portland Waterways Management at (503) 247–4015.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone for the Oregon Symphony Celebration Fireworks Display in 33 CFR 165.1315(a)(7) on August 28, 2008 from 8:30 p.m. to 11:30 p.m.

Under the provisions of 33 CFR 165.1315, a vessel may not enter the regulated area, unless it receives permission from the Captain of the Port (COTP) or his designated representative. The Coast Guard may be assisted by other Federal, state, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 165.1315 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and a marine information broadcast. If the COTP determines that the regulated area need not be enforced for the full duration stated in this notice, he may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: August 13, 2008.

F.G. Myer,

Captain, U.S. Coast Guard, Captain of the Port Portland.

[FR Doc. E8–19531 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2008–0759]

RIN 1625–AA00

Safety Zone; American Music Festival; Chesapeake Bay, Virginia Beach, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a 420-foot radius safety zone on the Chesapeake Bay in the vicinity of the Virginia Beach Oceanfront, Virginia Beach, VA in support of the American Music Festival Fireworks event. This action is intended to protect mariners from the hazards associated with fireworks displays by restricting vessel traffic movement in the vicinity of the event.

DATES: This rule is effective from August 29, 2008 at 10 p.m. until August 31, 2008 at 11 p.m.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0759 and are available online at *http://www.regulations.gov.* They are also available for inspection or copying in two locations: The Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; and the Sector Hampton Roads, Norfolk Federal Building, 200 Granby St., 7th Floor, Norfolk, VA 23510 between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call LT Tiffany Duffy, Chief Waterways Management Division, Sector Hampton Roads at (757) 668–5580. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest since immediate action is needed to provide for the safety of life and property on navigable waters. Additionally, this temporary safety zone will only be enforced for 1 hour on August 29, 2008 and for 1 hour on August 31, 2008 and should have minimal impact on vessel transits due to the fact that vessels can safely transit through the zone when authorized by the Captain of the Port or his Representative and that they are not precluded from using any portion of the waterway except the safety zone area itself. For the same reasons above, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

On August 29 and August 31, 2008, Dominion Fireworks will sponsor a fireworks display on the Chesapeake Bay shoreline centered on position 36°49′58″ N/75°57′57″ W (NAD 1983). Due to the need to protect mariners and spectators from the hazards associated with the fireworks display, access will be temporarily restricted within 420 feet of the fireworks launch site.

Discussion of Rule

The Coast Guard is establishing a safety zone on the navigable waters of the Chesapeake Bay within 420 feet of position 36°49′58″ N/075°57′57″ W (NAD 1983). This safety zone will be established in the vicinity of Virginia Beach, VA on August 29, 2008 at 10 p.m. to August 31, 2008 at 11 p.m. In the interest of public safety, access to the safety zone will be restricted from 10 p.m. to 11 p.m. on August 29, 2008 and from 10 p.m. to 11 p.m. on August 31, 2008. Except for participants and vessels authorized by the Coast Guard Captain of the Port or his representative, no person or vessel may enter or remain in the regulated area.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. Although this regulation restricts access to the safety zone, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the zone is of limited size; and (iii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor within the specified zone during the enforcement periods.

The safety zone will not have a significant economic impact on a substantial number of small entities because the zone will only be enforced for a limited time and is of limited size. Additionally, vessel traffic can pass safely around the zone. Before the effective period, maritime advisories will be issued and made widely available to waterway users.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 5100.1 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded under the Instruction that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

An environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3300, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6 and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1

■ 2. Add temporary § 165.T05–0759, to read as follows:

§ 165.T05–0759 Safety Zone: American Music Festival Fireworks Event, Chesapeake Bay, Virginia Beach, VA.

(a) *Regulated area.* The following area is a safety zone: All navigable waters of the Captain of the Port Sector Hampton Roads zone, as defined in 33 CFR 3.25–10, in the vicinity of the Virginia Beach Oceanfront in Virginia Beach, VA and within 420 feet of position 36°49′58″ N / 75°57′57″ W (NAD 1983).

(b) *Definitions.* As used in this section, Captain of the Port Representative means any U.S. Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Hampton Roads, Virginia to act on his behalf.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(2) The operator of any vessel in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(3) The Captain of the Port, Hampton Roads and the Sector Duty Officer at Sector Hampton Roads in Portsmouth, Virginia can be contacted at telephone number (757) 668–5555 or (757) 484–8192.

(4) The Captain of the Port Representative enforcing the safety zone can be contacted on VHF–FM marine band radio, channel 13 (156.65 Mhz) and channel 16 (156.8 Mhz).

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(e) *Enforcement period.* This rule is effective on August 29, 2008 from 10 p.m. to 11 p.m. and on August 31, 2008 from 10 p.m. to 11 p.m.

Dated: July 30, 2008.

Patrick B. Trapp,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. E8–19533 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–OAR–R04–2008–0512–200815 (a); FRL–8706–4]

Approval and Promulgation of Plans; North Carolina: Miscellaneous Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the State Implementation Plan (SIP) submitted by the North Carolina Department of Environment and Natural Resources (NCDENR) on behalf of the State of North Carolina on April 16, 2001, April 4, 2003, and December 14, 2004. The purpose of these revisions is to require that continuous emissions monitoring systems be used to determine compliance; specify a 24-hour block averaging time for sulfur dioxide emissions; make a correction to a cross-reference; provide options for supplying missing data and for determining heat input; and make several revisions to permit exemptions. This action is being taken pursuant to section 110 of the Clean Air Act (CAA).

DATES: This direct final rule is effective October 21, 2008 without further notice, unless EPA receives adverse comment by September 22, 2008. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–OAR–R04–2008–0512 by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: ward.nacosta@epa.gov.*

3. *Fax:* (404) 562–9019.

4. *Mail:* ''EPA–OAR–R04–2008–0512,'' Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

5. *Hand Delivery or Courier:* Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

Instructions: Direct your comments to Docket ID No. ''EPA–OAR–R04–2008–0512.'' EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov* or e-mail, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR**

FURTHER INFORMATION CONTACT section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140. Ms. Ward can also be reached via electronic mail at *ward.nacosta@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. EPA's Action
II. Analysis of the State's Submittals
III. Final Action
IV. Statutory and Executive Order Reviews

I. EPA's Action

EPA is taking direct final action to approve multiple revisions for several rules submitted by NCDENR on April 16, 2001, April 4, 2003, and December 14, 2004. The revisions were submitted to update the SIP with State rule changes. The rule changes support North Carolina's plan for attainment and maintenance of the NAAQS. The rule changes now being incorporated into the SIP are as follows:

a. 15A North Carolina Administrative Code (NCAC) subchapter 2D, section .0519, ''Emission Control Standards; Control of Nitrogen Dioxide and Nitrogen Oxides'' (submitted December 14, 2004, and effective January 1, 2005);

b. 15A NCAC subchapter 2D, section .0606, ''Monitoring: Recordkeeping: Reporting; Sources Covered by Appendix P of 40 CFR part 51'' (submitted April 16, 2001, April 4, 2003, and December 14, 2004, and effective January 1, 2005);

c. 15A NCAC subchapter 2D, section .0608, ''Monitoring/Recordkeeping/ Reporting; Other Large Coal or Residual Oil Burners'' (submitted April 16, 2001, April 4, 2003, and December 14, 2004, and effective January 1, 2005);

d. 15A NCAC subchapter 2D, section .1404, ''Nitrogen Oxides; Recordkeeping: Reporting: Monitoring'' (submitted December 14, 2004, and effective January 1, 2005); and

e. 15A NCAC subchapter 2Q, section .0102, ''Air Quality Permits Procedures; Activities Exempted from Permit Requirements'' (submitted December 14, 2004, and effective January 1, 2005).

II. Analysis of State's Submittal

The following analysis is in the order of the rules noted above.

a. 15A NCAC, subchapter 2D, section .0519 is being revised to remove an incorrect cross-reference in the paragraph which specifies how to calculate the allowable emission limit for boilers that burn both coal and oil or gas.

b. and c. 15A NCAC, subchapter 2D, sections .0606 and .0608 are being revised to require continuous emission monitoring systems (CEMS) be used to determine compliance for sources covered by Appendix P of 40 CFR part 51 and other large coal or residual oil burners if these sources are required to use CEMS under another State or federal rule and to specify a 24-hour averaging time for sulfur dioxide emissions to determine compliance. These rules were revised to provide facilities an alternative method of sampling coal and fuel oil instead of sampling each fuel shipment individually. This revision was made to improve the quality of reported sulfur dioxide emissions estimates. The final revision to these rules allow for a different procedure or methodology other than those specified by sections .0606 and .0608 to be used if certain conditions are met, specifying the procedures for requesting these alternative methodologies and approval of the request to utilize them. These rules currently contain specific procedures and methodologies for how to monitor sulfur dioxide emissions for fossil fuel-fired steam generators, nitric acid plants, sulfuric acid plants, petroleum refineries, and other large coal or residual oil burners.

d. 15A NCAC, subchapter 2D .1404 is being revised to include options for supplying missing data and determining heat input. This revision allows the owner or operator of the source to avoid having to supply missing data if it can be documented that the source and its control device were being properly operated when the monitoring measurements are missing.

e. 15A NCAC, subchapter 2Q .0102 is being revised to make changes to several permit exemptions. Those permit exemptions pertain to petroleum dry cleaners, small fuel combustion sources which primarily combust wood, and emergency generators. Revisions to this section make corrections to a cross-reference and typographical errors and also includes a clarification that to qualify for the permit exemption, the exempted sources at a facility must not be in violation of any applicable emission standard.

III. Final Action

EPA is taking direct final action to approve the aforementioned revisions, specifically, subchapter 2D, sections .0519, .0606, .0608, and .1404, and subchapter 2Q, section .0102 into the North Carolina SIP. These revisions were submitted by NCDENR on April 16, 2001, April 4, 2003, and December 14, 2004.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective October 21, 2008 without further notice unless the Agency receives adverse comments by September 22, 2008.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on October 21, 2008 and no further action will be taken on the proposed rule.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities

under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 21, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See, section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: August 6, 2008.

Russell L. Wright, Jr.,

Acting Deputy Regional Administrator, Region 4.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart II—North Carolina

■ 2. In § 52.1770(c), table 1 is amended:

(a) Under subchapter 2D by revising the entries for ''.0519 Control of Nitrogen Dioxide and Nitrogen Oxides,'' ''.0606 Sources Covered by Appendix P of 40 CFR Part 51,'' ''.0608 Other Large Coal or Residual Oil Burners,'' ''.1404 Recordkeeping: Reporting: Monitoring''; and

(b) Under subchapter 2Q by revising the entry for ''.0102 Activities Exempted from Permit Requirements'' to read as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

TABLE 1—EPA APPROVED NORTH CAROLINA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
Subchapter 2D Air Pollution Control Requirements				
* *	* *	*	*	*
Sect. 0519	Control of Nitrogen Dioxide and Nitrogen Oxides.	01/01/05	08/22/08	
* *	* *	*	*	*
Sect. 0606	Sources Covered by Appendix P of 40 CFR part 51.	01/01/05	08/22/08	
* *	* *	*	*	*
Sect. 0608	Other Large Coal or Residual Oil Burners.	01/01/05	08/22/08	
* *	* *	*	*	*
Sect. 1404	Recordkeeping: Reporting: Monitoring	01/01/05	08/22/08	
* *	* *	*	*	*
Subchapter 2Q Air Quality Permits				
* *	* *	*	*	*
Sect. 0102	Activities Exempted from Permit Requirements.	01/01/05	08/22/08	

TABLE 1—EPA APPROVED NORTH CAROLINA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*

[FR Doc. E8–19192 Filed 8–21–08; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 522

[GSAR Amendment 2008–01; GSAR Case 2006–G505; (Change 22); Correction; Docket FAR–2008—0007; Sequence 1]

General Services Administration Acquisition Regulation; Correction

AGENCIES: General Services Administration (GSA), Office of the Chief Acquisition Officer.

ACTION: Correction.

SUMMARY: The General Services Administration (GSA) is issuing a correction to GSAR Amendment 2008–01; GSAR Case 2006–G505; (Change 22), which was published in the **Federal Register** at 73 FR 46202, August 8, 2008.

DATES: Effective Date: August 22, 2008.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat (VPR), Room 4041, GS Building, Washington, DC, 20405, (202) 501–4755, for information pertaining to status or publication schedules. For clarification of content, contact Mr. Ernest Woodson, Procurement Analyst, at (202) 501–3775. Please cite GSAR Amendment 2008–01; GSAR Case 2006–G505; (Change 22); Correction.

Correction

In the final rule document appearing in the issue of August 8, 2008:

1. On page 46202, second column, last paragraph under ''Background,'' remove ''deleted in its entirety because of its potential for conflict'' and add ''revised to ensure consistency'' in its place.

Dated: August 18, 2008.

Laurieann Duarte,

Acting Director, Regulatory Secretariat.

[FR Doc. E8–19501 Filed 8–21–08; 8:45 am]

BILLING CODE 6820–61–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 080310408–81008–02]

RIN 0648–AW55

Marine Mammals; Subsistence Taking of Northern Fur Seals; Harvest Estimates

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

ACTION: Final estimates of annual fur seal subsistence needs.

SUMMARY: Pursuant to the regulations governing the subsistence taking of northern fur seals, NMFS is publishing the annual fur seal subsistence harvests on St. George and St. Paul Islands (the Pribilof Islands) for 2005 to 2007, and the annual estimates for the fur seal subsistence needs for 2008 through 2010. NMFS estimates the annual subsistence needs are 1,645–2,000 seals on St. Paul and 300–500 seals on St. George.

DATES: Effective September 22, 2008.

FOR FURTHER INFORMATION CONTACT: Michael Williams, (907) 271–5117, email *Michael.Williams@noaa.gov*; Kaja Brix, (907) 586–7824, email *Kaja.Brix@noaa.gov*; or Tom Eagle, (301) 713–2322, ext. 105, email *Tom.Eagle@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Electronic Access

A Final Environmental Impact Statement is available on the Internet at the following address: *http://www.fakr.noaa.gov/protectedresources/seals/fur.htm*.

The subsistence harvest from the depleted stock of northern fur seals on the Pribilof Islands, AK, is governed by regulations found in 50 CFR part 216, subpart F, Taking for Subsistence Purposes. The regulations require NMFS to publish every 3 years a summary of the harvest in the preceding 3 years and a discussion of the number of fur seals expected to be taken over the next 3 years to satisfy the subsistence requirements of residents of the Pribilof Islands (St. Paul and St. George). After a 30-day comment period, NMFS must publish a final notification of the expected annual harvest levels for the next 3 years.

On June 3, 2008 (73 FR 31666), NMFS published the summary of the 2005–2007 fur seal harvests and provided a 30-day comment period on proposed estimates of subsistence needs for 2008–2010. One comment letter was received on the proposed estimates. The letter identified one substantive point: The northern fur seal harvest is unnecessary. NMFS responds that the harvest of northern fur seals meets the dietary and cultural needs of the Pribilof Island Alaska Native residents (Pribilovians). The harvest is authorized by the Fur Seal Act and the Marine Mammal Protection Act and continues a tradition as reported in numerous government documents dating back to the late 1800s. NMFS estimates the annual subsistence needs are 1,645–2,000 juvenile male fur seals on St. Paul and 300–500 juvenile male fur seals on St. George. Background information related to these estimates was included in the proposed harvest estimates published in the **Federal Register** on June 3, 2008.

Classification

National Environmental Policy Act

NMFS prepared an EIS evaluating the impacts on the human environment of the subsistence harvest on northern fur seals. The final EIS is available on the Internet (see Electronic Access).

Executive Order 12866 and Regulatory Flexibility Act

This action has been determined to be not significant under Executive Order (E.O.) 12866. The Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy of the Small Business Administration at the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. Because the harvest of northern fur seals on the Pribilof Islands, AK, is for subsistence purposes only, the estimate of subsistence need would not have an economic effect on any small entities.

Therefore, a regulatory flexibility analysis was not prepared.

Paperwork Reduction Act

This action does not require the collection of information.

Executive Order 13132

This action does not contain policies with federalism implications under E.O. 13132.

Executive Order 12898, Section 4–4, Subsistence Consumption of Fish and Wildlife.

Section 4–4, Executive Order 12898, requires Federal agencies to protect populations who consume fish and wildlife as part of their subsistence lifestyle, and to communicate to the public the potential health risks [from contaminants] involved as a result of eating fish and wildlife. NMFS has monitored and evaluated contaminant loads in northern fur seals in Alaska for nearly a decade and has reported this information to the Alaska Department of Health and Social Service, and to Alaska Native communities, as this information becomes available.

Executive Order 13175

Executive Order 13175 of November 6, 2000 (25 U.S.C. 450 Note), the executive Memorandum of April 29, 1994 (25 U.S.C. 450 note), and the American Indian Native Policy of the U.S. Department of Commerce (March 30, 1995) outline the responsibilities of the National Marine Fisheries Service in matters affecting tribal interests. Section 161 of Public Law 108–100 (188 Stat. 452) as amended by section 518 of Public Law 108–447 (118 Stat. 3267), extends the consultation requirements of E.O. 13175 to Alaska Native corporations. NMFS has contacted the tribal governments of St. Paul and St. George Islands and their respective local Native corporations (Tanadgusix and Tanaq) about setting the next three years harvest estimates and received their input. NMFS signed cooperative agreements with the tribal governments of St. Paul Island in 2000 and with St. George Island in 2001 pursuant to section 119 of the MMPA.

Dated: August 18, 2008.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. E8–19584 Filed 8–21–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 060418103–6181–02]

RIN 0648–XJ82

Fisheries of the Northeastern United States; Spiny Dogfish Fishery; Commercial Period 1 Quota Harvested

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

ACTION: Closure of spiny dogfish fishery.

SUMMARY: NMFS announces that the spiny dogfish commercial quota available to the coastal states from Maine through Florida for the semi-annual quota period, May 1, 2008 - October 31, 2008, has been harvested. Therefore, effective 0001 hours, August 20, 2008, federally permitted spiny dofish vessels may not fish for, possess, transfer, or land spiny dogfish until November 1, 2008, when the Period 2 quota becomes available. Regulations governing the spiny dogfish fishery require publication of this notification to advise the coastal states from Maine through Florida that the quota has been harvested and to advise vessel permit holders and dealer permit holders that no Federal commercial quota is available for landing spiny dogfish in these states. This action is necessary to prevent the fishery from exceeding its Period 1 quota and to allow for effective management of this stock.

DATES: Quota Period 1 for the spiny dogfish fishery is closed effective at 0001 hr local time, August 20, 2008, through 2400 hr local time October 31, 2008. Effective August 20, 2008, federally permitted dealers are also advised that they may not purchase spiny dogfish from federally permitted spiny dogfish vessels.

FOR FURTHER INFORMATION CONTACT: Don Frei, Fisheries Management Specialist, at (978) 281–9221, or *Don.Frei@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Regulations governing the spiny dogfish fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota, which is allocated into two quota periods based upon percentages specified in the fishery management plan. The commercial quota is distributed to the coastal states from Maine through Florida, as described in § 648.230.

The initial total commercial quota for spiny dogfish for the 2008 fishing year is 4 million lb (1.81 million kg) (71 FR 40436, July 17, 2006). The commercial quota is allocated into two periods (May 1 through October 31, and November 1 through April 30). Vessel possession limits are intended to preclude directed fishing, and they are set at 600 lb (272 kg) for both Quota Periods 1 and 2. Quota Period 1 is allocated 2.3 million lb (1.05 million kg)), and Quota Period 2 is allocated 1.7 million lb (763,849 kg) of the commercial quota. The total quota cannot be exceeded, so landings in excess of the amount allocated to Period 1 have the effect of reducing the quota available to the fishery during Period 2.

The Administrator, Northeast Region, NMFS (Regional Administrator) monitors the commercial spiny dogfish quota for each quota period and, based upon dealer reports, state data, and other available information, determines when the total commercial quota will be harvested. NMFS is required to publish a notification in the **Federal Register** advising and notifying commercial vessels and dealer permit holders that, effective upon a specific date, the Federal spiny dogfish commercial quota has been harvested and no Federal commercial quota is available for landing spiny dogfish for the remainder of that quota period.

Section 648.4(b) provides that Federal spiny dogfish permit holders agree, as a condition of the permit, not to land spiny dogfish in any state after NMFS has published notification in the **Federal Register** that the commercial quota has been harvested and that no commercial quota for the spiny dogfish fishery is available. Therefore, effective 0001 hr local time, August 20, 2008, landings of spiny dogfish in coastal states from Maine through Florida by vessels holding commercial Federal fisheries permits are prohibited through October 31, 2008, 2400 hr local time. The 2008 Period 2 quota will be available for commercial spiny dogfish harvest on November 1, 2008. Effective August 20, 2008, federally permitted dealers are also advised that they may not purchase spiny dogfish from vessels issued Federal spiny dogfish permits that land in coastal states from Maine through Florida.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 18, 2008.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E8–19426 Filed 8–18–08; 4:15 pm]

BILLING CODE 3510–22–S′

Proposed Rules

Federal Register
Vol. 73, No. 164
Friday, August 22, 2008

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 915

[Docket No. AMS–FV–08–0058; FV08–915–2]

Avocados Grown in South Florida; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible Florida avocados growers to determine whether they favor continuance of the marketing order regulating the handling of avocados grown in South Florida.

DATES: The referendum will be conducted from September 22 to October 6, 2008. To vote in this referendum, growers must have been producing Florida avocados within the designated production area during the period April 1, 2007, through March 31, 2008.

ADDRESSES: Copies of the marketing order may be obtained from the Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, U.S. Department of Agriculture, 799 Overlook Dr. Suite A, Winter Haven, FL 33884–1671, or the Office of the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237.

FOR FURTHER INFORMATION CONTACT: William G. Pimental, Marketing Specialist, or Christian D. Nissen, Regional Manager, Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; *Telephone:* (863) 324–3375, *Fax:* (863) 325–8793 or *E-mail: William.Pimental@usda.gov* or *Christian.Nissen@usda.gov,* respectively.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 915 (7 CFR part 915), hereinafter referred to as the ''order,'' and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act,'' it is hereby directed that a referendum be conducted to ascertain whether continuance of the order is favored by growers. The referendum shall be conducted from September 22 to October 6, 2008, among eligible Florida avocado growers in the production area. Only growers that were engaged in the production of Florida avocados during the period of April 1, 2007, to March 31, 2008, may participate in the continuance referendum.

USDA has determined that continuance referenda are an effective means for determining whether growers favor the continuation of marketing order programs. USDA would consider termination of the order if less than two-thirds of the growers voting in the referendum, and growers of less than two-thirds of the volume of Florida avocados represented in the referendum favor continuance of their program. In evaluating the merits of continuance versus termination, USDA will consider the results of the continuance referendum and other relevant information regarding operation of the order. USDA will evaluate the order's relative benefits and disadvantages to growers, handlers, and consumers to determine whether continuing the order would tend to effectuate the declared policy of the Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the ballot materials used in the referendum herein ordered, have been approved by the Office of Management and Budget (OMB), under OMB No. 0581–0189, OMB Generic Fruit Crops. It has been estimated that it will take an average of 5 minutes for each of the approximately 300 production area growers of Florida avocados to cast a ballot. Participation is voluntary. Ballots postmarked after October 6, 2008, will not be included in the vote tabulation.

Christian D. Nissen and William G. Pimental of the Southeast Marketing Field Office, Fruit and Vegetable Programs, AMS, USDA, are hereby designated as the referendum agents of the Secretary of Agriculture to conduct this referendum. The procedure applicable to the referendum shall be the ''Procedure for the Conduct of Referenda in Connection With Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended'' (7 CFR 900.400 *et seq.*).

Ballots will be mailed to all growers of record and may also be obtained from the referendum agents, or from their appointees.

List of Subjects in 7 CFR Part 915

Avocados, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 601–674.

Dated: August 18, 2008.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E8–19467 Filed 8–21–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0752; Directorate Identifier 2008–NE–22–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada (P&WC) JT15D–5; –5B; –5F; and –5R Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as follows:

There have been several reported incidents of high altitude, dual engine flameout on JT15D–5 engines powered aircraft operating in certain meteorological conditions. Subsequent to the investigation of incidents,

review of the engine design has revealed that the Fuel Control Hydro Mechanical Unit (HMU) P3 servo can be exposed to excessive moisture and freezing.

We are proposing this AD to prevent engine flameout, and possible dual-engine flameout events, caused by excessive moisture and freezing in the P3 servo, during certain flight conditions.

DATES: We must receive comments on this proposed AD by September 22, 2008.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail*: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery*: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax*: (202) 493–2251.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Ian Dargin, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park; Burlington, MA 01803; *e-mail*: *ian.dargin@faa.gov*; telephone (781) 238–7178; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0752; Directorate Identifier 2008–NE–22–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Discussion

Transport Canada, which is the aviation authority for Canada, has issued Canadian AD CF–2008–23, dated June 27, 2008 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states the following:

> There have been several reported incidents of high altitude, dual engine flameout on JT15D–5 engine powered aircraft operating in certain meteorological conditions. Subsequent to the investigation of incidents, review of the engine design has revealed that the Fuel Control HMU P3 servo can be exposed to excessive moisture and freezing. To preclude P3 servo freezing, P&WC has issued JT15D ASB No. JT15D–72–A7611 to re-route compressor delivery air to the HMU and improve moisture separation.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

P&WC has issued ASB No. JT15D–72–A7611, Revision 1, dated June 16, 2008. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of Canada, and is approved for operation in the United States. Pursuant to our bilateral agreement with Canada, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all the information provided by Canada and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD requires replacing the compressor air to HMU delivery tube with a new, re-routed tube. The new tube provides warmer and dryer P3 air, improves moisture separation, and directs the moisture away from the HMU through a drain hole.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 1,500 products of U.S. registry. We also estimate that it would take about 3 work-hours per product to comply with this proposed AD. The average labor rate is $80 per work-hour. Required parts would cost about $1,981 per product for JT15D–5 and –5R engines, and $3,169 per product for JT15D–5B and –5R engines. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $4,222,500. Our cost estimate is exclusive of possible warranty coverage.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative,

on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Pratt & Whitney Canada: Docket No. FAA–2008–0752; Directorate Identifier 2008–NE–22–AD.

Comments Due Date

(a) We must receive comments by September 22, 2008.

Affected Airworthiness Directives (ADs)

(b) None.

Applicability

(c) This AD applies to the following Pratt & Whitney Canada (P&WC) turbofan engines with compressor air to HMU delivery tube, part number (P/N) 3119150–01 installed:

(1) JT15D–5 turbofan engines, serial numbers (SNs) below and including SN PCE–100411.

(2) JT15D–5 turbofan engines, SNs below and including SN PCE–JA0818.

(3) All JT15D–5B turbofan engines.

(4) All JT15D–5F turbofan engines.

(5) JT15D–5R turbofan engines SNs below and including SN PCE–JG0104.

(6) All JT15D–5 turbofan engines converted to model JT15D–5R by incorporation of P&WC Service Bulletin No. 7605.

These engines are installed on, but not limited to, Cessna models 500; 501; 550; 551; S550; 560; and 560 Ultra airplanes; Mitsubishi models 300 and 300–10 airplanes; and Hawker Beechcraft models 400; 400A; and 400T airplanes.

Reason

(d) Transport Canada AD CF–2008–23, dated June 27, 2008, states:

There have been several reported incidents of high altitude, dual engine flameout on JT15D–5 engines powered aircraft operating in certain meteorological conditions. Subsequent to the investigation of incidents, review of the engine design has revealed that the Fuel Control Hydro Mechanical Unit (HMU) P3 servo can be exposed to excessive moisture and freezing. To preclude P3 servo freezing, P&WC has issued JT15D Alert Service Bulletin (ASB) JT15D–72–A7611 to re-route compressor delivery air to the HMU and improve moisture separation. Considering the potentially hazardous consequence of possible in-flight dual engine flameout, this airworthiness directive is issued to mandate the incorporation of P&WC ASB JT15D–72–A7611 to the affected JT15D–5 engines, in order to minimize the possibility of this hazard.

We are issuing this AD to prevent engine flameout, and possible dual-engine flameout events, caused by excessive moisture and freezing in the P3 servo, during certain flight conditions.

Actions and Compliance

(e) Unless already done, do the following actions.

(1) Within 200 flight hours after the effective date of this AD or by December 31, 2008, whichever occurs first, remove from service compressor air to HMU delivery tube, P/N 3119150–01.

(2) Install a serviceable compressor air to HMU delivery tube.

(3) Tube installation in accordance with P&WC Alert Service Bulletin (ASB) No. JT15D–72–A7611, Revision 1, dated June 16, 2008, meets the requirements of this AD.

Prohibition of Compressor Air to HMU Delivery Tube, P/N 3119150–01

(4) After the effective date of this AD, do not install any compressor air to HMU delivery tube, P/N 3119150–01, onto any engine.

Definition

(f) For the purpose of this AD, a serviceable compressor air to HMU delivery tube is a compressor air to HMU delivery tube that is other than the old/removed tube part number listed in this AD.

(g) *Alternative Methods of Compliance (AMOCs)*: The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Previous Credit

(h) Replacement of the compressor air to HMU delivery tube using P&WC ASB No. JT15D–72–A7611, dated March 26, 2008, before the effective date of this AD, meets the requirements of this AD.

Related Information

(i) Refer to Transport Canada AD CF–2008–23, dated June 27, 2008, for related information.

(j) Contact Ian Dargin, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park; Burlington, MA 01803; *e-mail*: *ian.dargin@faa.gov*; telephone (781) 238–7178; fax (781) 238–7199, for more information about this AD.

Issued in Burlington, Massachusetts, on August 15, 2008.

Robert G. Mann,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E8–19390 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Parts 4, 531, 553, 778, 779, 780, 785, 786, and 790

RIN 1215–AB13

Updating Regulations Issued Under the Fair Labor Standards Act

AGENCY: Wage and Hour Division, Employment Standards Administration, Department of Labor.

ACTION: Extension of comment period on proposed regulations.

SUMMARY: This document extends the period for filing written comments for an additional 15 days on proposed revisions to regulations issued under the Fair Labor Standards Act of 1938 (FLSA) and the Portal-to-Portal Act of 1947 (Portal Act) that have become out of date because of subsequent legislation or court decisions. The Department of Labor is taking this action in order to provide interested parties additional time to submit comments.

DATES: Comments must be received on or before September 26, 2008.

ADDRESSES: You may submit comments, identified by RIN 1215–AB13, by either one of the following methods:

- *Electronic comments, through the federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue, NW., Washington, DC 20210.

Instructions: Please submit one copy of your comments by only one method. All submissions received must include the agency name and Regulatory Information Number (RIN) identified above for this rulemaking. Comments received will be posted to *http://www.regulations.gov,* including any personal information provided. Because we continue to experience delays in receiving mail in the Washington, DC, area, commenters are strongly encouraged to transmit their comments electronically via the federal eRulemaking Portal at *http://www.regulations.gov* or to submit them

by mail early. For additional information on submitting comments and the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to the federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Richard M. Brennan, Director, Office of Interpretations and Regulatory Analysis, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S–3506, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–0051 (this is not a toll-free number). Copies of this notice may be obtained in alternative formats (Large Print, Braille, Audio Tape or Disc), upon request, by calling (202) 693–0023 (not a toll-free number). TTY/TDD callers may dial toll-free (877) 889–5627 to obtain information or request materials in alternative formats.

Questions of interpretation and/or enforcement of regulations issued by this agency or referenced in this notice may be directed to the nearest Wage and Hour Division (WHD) District Office. Locate the nearest office by calling our toll-free help line at (866) 4USWAGE ((866) 487–9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto the WHD's Web site for a nationwide listing of Wage and Hour District and Area Offices at: *http://www.dol.gov/esa/contacts/whd/america2.htm.*

SUPPLEMENTARY INFORMATION:

I. Electronic Access and Filing Comments

Public Participation: This notice is available through the **Federal Register** and the *http://www.regulations.gov* Web site. You may also access this notice via the WHD home page at *http://www.dol.gov/esa/whd/regulations/FLSA2008.htm.* To comment electronically on federal rulemakings, go to the federal eRulemaking Portal at *http://www.regulations.gov,* which will allow you to find, review, and submit comments on federal documents that are open for comment and published in the **Federal Register**. Please identify all comments submitted in electronic form by the RIN docket number (1215–AB13). Because of delays in receiving mail in the Washington, DC, area, commenters should transmit their comments electronically via the federal eRulemaking Portal at *http://www.regulations.gov,* or submit them by mail early to ensure timely receipt prior to the close of the comment period. Submit one copy of your comments by only one method.

II. Request for Comment

In the **Federal Register** of July 28, 2008 (73 FR 43654), the Department of Labor published a notice of proposed rulemaking requesting public comments on proposed revisions to update existing outdated regulatory provisions under the FLSA and the Portal Act. The proposed revisions are intended to conform the regulations to FLSA amendments passed in 1974, 1977, 1996, 1997, 1998, 1999, 2000, and 2007, a Portal Act amendment passed in 1996, and to several authoritative federal appellate court rulings that have invalidated portions of the existing regulations. Interested parties were requested to submit comments on or before September 11, 2008.

The Department has received requests to extend the period for filing public comments from representatives of the following organizations: American Federation of Labor and Congress of Industrial Organizations; National Employment Lawyers Association; National Employment Law Project; International Association of Fire Fighters; American Federation of State, County and Municipal Employees, AFL–CIO; and Service Employees International Union CTW, CLC. Because of the interest that has been expressed in this matter, the Department has decided to extend the period for submitting public comments for 15 additional days, to September 26, 2008.

Signed at Washington, DC this 18th day of August 2008.

Victoria A. Lipnic,

Assistant Secretary, Employment Standards Administration.

Alexander J. Passantino,

Acting Administrator, Wage and Hour Division.

[FR Doc. E8–19475 Filed 8–21–08; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2008–0697]

RIN 1625–AA09

Drawbridge Operation Regulation; Intracoastal Waterway (ICW), Barnegat Bay, Seaside Heights, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the drawbridge operation regulations of the S37 Bridge, at ICW mile 14.1, across Barnegat Bay at Seaside Heights, NJ. This proposal would allow the drawbridge to operate on an advance notice basis during specific times of the year. The proposed change would result in more efficient use of the bridge during months of infrequent transit.

DATES: Comments and related material must reach the Coast Guard on or before October 6, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2008–0697 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Terrance A. Knowles, Environmental Protection Specialist, Fifth Coast Guard District, at (757) 398–6587. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number for this

rulemaking (USCG–2008–0697), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time. Enter the docket number for this rulemaking (USCG–2008–0697) in the Search box, and click ''Go>>.'' You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays or at Commander (dpb), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 233704–5004 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov.*

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The New Jersey Department of Transportation (NJDOT) is responsible for the operation of the S37 Bridge, at ICW mile 14.1, across Barnegat Bay at Seaside Heights, NJ. NJDOT requested advance notification for vessel openings from December 1 to March 31 from 8 a.m. to 11 p.m. for the drawbridge due to the infrequency of requests.

In the closed-to-navigation position, the S37 Bridge, at ICW mile 14.1, across Barnegat Bay at Seaside Heights, has a vertical clearance of 30 feet, above mean high water. The existing operating regulation for the drawbridge is set out in 33 CFR 117.733(c), which requires the bridge to open on signal except from December 1 through March 31 from 11 p.m. to 8 a.m., the draw need not be opened; from April 1 through November 30, from 11 p.m. to 8 a.m. the draw shall open if at least four hours notice is given; and from Memorial Day through Labor Day from 8 a.m. to 8 p.m., the draw need only open on the hour and half hour.

A review of the bridge logs for 2005 to 2007 supplied by NJDOT revealed that, from December 1 through March 31, between 8 a.m. to 11 p.m., the drawbridge opened for vessels a total of 5, 9, and 35 times per year, respectively. The year of 2007 was an anomaly, based on unseasonably warm weather for the winter months.

Due to the infrequency of requests for vessel openings during the winter months, NJDOT requested to change the current operating regulations from December 1 through March 31 of every year from 8 a.m. to 11 p.m. by requiring the draw span to open on signal if at least four hours notice is given.

Discussion of Proposed Rule

The Coast Guard proposes to amend 33 CFR § 117.733(c) which governs the S37 Bridge across Barnegat Bay, at ICW mile 14.1, at Seaside Heights, NJ, by revising paragraph (c)(1) to read that from December 1 to March 31 the draw shall open on signal if at least four hours notice is given. The change is due to the infrequency of requests for vessel openings during the winter months.

Regulatory Analysis

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary. We reached this conclusion based on the fact that the proposed changes have only a minimal impact on maritime traffic transiting the bridge. Mariners can plan their trips in accordance with the scheduled bridge openings, to minimize delays and vessels that can pass under the bridges without a bridge opening may do so at all times.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule could affect the following entities, some of which might be small entities: The owners or operators of vessels, unable to transit under the bridge, needing to transit the bridge on December 1 through March 31 from 8 a.m. until 11 p.m.

This proposed rule would not have a significant economic impact on a substantial number of small entities because the rule only adds minimal restrictions to the movement of navigation, mariners who plan their transits in accordance with the scheduled bridge openings and/or by giving timely notice can minimize delay and vessels that can pass under the bridges without a bridge opening may continue to do so at all times.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it,

please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Waverly W. Gregory, Jr., Bridge Administrator, Fifth Coast Guard District, (757) 398–6222. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D and the Department of Homeland Security Management Directive 5100.1, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment because it simply promulgates the operating regulations or procedures for drawbridges. See paragraph 32(e) of Commandant Instruction M16475.1D. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117 Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

2. Revise § 117.733(c)(1) to read as follows:

§ 117.733 New Jersey Intracoastal Waterway.

* * * * *

(c) * * *

(1) From December 1 through March 31, the draw need only open if at least four hours notice is given.

* * * * *

Dated: July 28, 2008.

Fred M. Rosa, Jr.,

Rear Admiral, United States Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. E8–19530 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–OAR–R04–2008–0512–200815 (b); FRL–8706–3]

Approval and Promulgation of Plans; North Carolina; Miscellaneous Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the State Implementation Plan submitted by the North Carolina Department of Environment and Natural Resources on behalf of the State of North Carolina on April 16, 2001, April 4, 2003, and December 14, 2004. The purpose of these revisions is to require continuous emissions monitoring systems be used to determine compliance; specify a 24-hour block averaging time for sulfur dioxide emissions; make a correction to a cross-reference; provide options for supplying missing data and for determining heat input; and make several revisions to permit exemptions. This action is being taken pursuant to section 110 of the Clean Air Act.

In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Written comments must be received on or before September 22, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–OAR–R04–2008–0512 by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: ward.nacosta@epa.gov.*

3. *Fax:* (404) 562–9019.

4. *Mail:* ''EPA–OAR–R04–2008–0512,'' Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

5. *Hand Delivery or Courier:* Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140. Ms. Ward can also be reached via electronic mail at *ward.nacosta@epa.gov.*

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the Rules Section of this **Federal Register**.

Dated: August 6, 2008.

Russell L. Wright, Jr.,

Acting Deputy Regional Administrator, Region 4.

[FR Doc. E8–19191 Filed 8–21–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–1907; MB Docket No. 08–127; RM–11459]

Television Broadcasting Services; Madison, WI

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a channel substitution proposed by WMSN Licensee, LLC (''WMSN''), the licensee of WMSN–DT, DTV channel 11, Madison, Wisconsin. WMSN requests the substitution of DTV channel 49 for channel 11 at Madison.

DATES: Comments must be filed on or before September 22, 2008, and reply comments on or before October 6, 2008.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 445 12th Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: Clifford M. Harrington, Esq., Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street, NW., Washington, DC 20037–1128.

FOR FURTHER INFORMATION CONTACT: David J. Brown, *david.brown@fcc.gov,* Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 08–127, adopted August 13, 2008, and released August 14, 2008. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via e-mail *http://www.BCPIWEB.com.* To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for

rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

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

§ 73.622(i) [Amended]

2. Section 73.622(i), the DTV Table of Allotments under Wisconsin, is amended by adding DTV channel 49 and removing DTV channel 11 at Madison.

Federal Communications Commission.

Clay C. Pendarvis

Associate Chief, Video Division, Media Bureau.

[FR Doc. E8–19543 Filed 8–21–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–1897; MB Docket No. 08–163; RM–11482]

Television Broadcasting Services; Yuma, AZ

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a channel substitution proposed by Pappas Arizona License, LLC (''Pappas''), the permittee of KWST–DT, DTV channel 16, Yuma, Arizona. Pappas requests the substitution of DTV channel 13 for channel 16 at Yuma.

DATES: Comments must be filed on or before September 22, 2008, and reply comments on or before October 6, 2008.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 445 12th Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: Kathleen Victory, Esq., Fletcher, Heald & Hildreth, PLC, 1300 North 17th Street, 11th Floor, Arlington, VA 22209.

FOR FURTHER INFORMATION CONTACT: Adrienne Y. Denysyk, *adrienne.denysyk@fcc.gov,* Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 08–163, adopted August 7, 2008, and released August 13, 2008. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via e-mail *http://www.BCPIWEB.com.* To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

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

§ 73.622(i) [Amended]

2. Section 73.622(i), the DTV Table of Allotments under Arizona, is amended by adding channel 13 and removing channel 16 at Yuma.

Federal Communications Commission.

Clay C. Pendarvis,

Associate Chief, Video Division, Media Bureau.

[FR Doc. E8–19542 Filed 8–21–08; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 21

[FWS–R9–MB–2007–0017; 91200–1231–9BPP]

RIN 1018–AV34

Migratory Bird Permits; Control of Muscovy Ducks, Revisions to the Waterfowl Permit Exceptions and Waterfowl Sale and Disposal Permits Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose changes in the regulations governing control of introduced migratory birds. The muscovy duck (*Cairina moschata*) occurs naturally only in southern Texas. It has been introduced in other locations, where it is considered an invasive species that sometimes creates problems through competition with native species, damage to property, and transmission of disease. We propose to revise 50 CFR part 21 to prohibit sale of muscovy ducks for hunting, and to allow their removal in locations in which the species does not occur naturally in the contiguous United States, Alaska, and Hawaii, and in U.S. territories and possessions. This will require a revision of § 21.14 (permit exceptions for captive-bred migratory waterfowl other than mallard ducks) and a revision of § 21.25 (waterfowl sale and disposal permits), and the addition of § 21.54, an order to allow control of muscovy ducks, their nests, and eggs. We also have rewritten the affected regulations to make them easier to understand.

DATES: Send comments on this proposal by October 21, 2008.

ADDRESSES: You may submit comments, identified as comments on RIN 1018–AV34, by either of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *U.S. Mail or hand delivery:* Public Comments Processing, Attention RIN 1018–AV34; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 North Fairfax Drive, Suite 222; Arlington, VA 22203–1610.

We will not accept e-mail or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information that you provide. See the Public Comments section below for more information.

FOR FURTHER INFORMATION CONTACT: Dr. George T. Allen, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 703–358–1825.

SUPPLEMENTARY INFORMATION:

Background

The Fish and Wildlife Service is the Federal agency delegated the primary responsibility for managing migratory birds. The delegation is authorized by the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703 *et seq.*), which implements conventions with Great Britain (for Canada), Mexico, Japan, and the Soviet Union (Russia).

We implement the MBTA through Federal regulations found in title 50 of the Code of Federal Regulations (CFR). In 50 CFR 10.13, we list all species of migratory birds protected by the MBTA that are subject to the regulations protecting migratory birds in title 50, subchapter B (Taking, Possession, Transportation, Sale, Purchase, Barter, Exportation, and Importation of Wildlife and Plants). In 50 CFR part 13 (General Permit Procedures) and part 21 (Migratory Bird Permits), regulations allow us to issue permits for certain activities otherwise prohibited in regard to migratory birds. In part 21, we issue permits for the taking, possession, transportation, sale, purchase, barter, importation, exportation, and banding and marking of migratory birds. In that part, we also provide certain exceptions to permit requirements for public, scientific, or educational institutions and establish depredation and control orders that provide limited exceptions to the MBTA.

Muscovy Duck

The muscovy is a large duck native to South America, Central America, and Mexico. Due to a recent northward expansion of the range of the species, there is a small natural population in four counties in southern Texas in which natural breeding has been confirmed. For that reason, we included this species in the proposed rule to revise the list of migratory birds found in 50 CFR 10.13 (71 FR 50193, Aug. 24, 2006; 71 FR 75188, Dec. 14, 2006). We anticipate adding the species to the list when we finalize the regulation. However, we will not make a final decision on the § 10.13 list before we make a final decision on this muscovy duck proposed rule.

The muscovy duck normally inhabits forested swamps and mangrove ponds, lakes and streams, and freshwater ponds near wooded areas. The species often roosts in trees at night. The hen usually lays her eggs in a tree hole or hollow. However, muscovy ducks will occasionally nest in abandoned nests of large birds such as ospreys or eagles, between palm tree fronds, and in wooden boxes or other man-made elevated cavities. The species does not form stable pairs.

Muscovy ducks can breed near urban and suburban lakes and on farms, nesting in tree cavities or on the ground, under shrubs in yards, on condominium balconies, or under roof overhangs. Feral populations, particularly in Florida, are said to present problems. Feral muscovy ducks are wary and associate little with other species.

Muscovy ducks feed on the roots, stems, leaves, and seeds of aquatic and terrestrial plants, including agricultural crops. They also eat small fishes, reptiles, crustaceans, insects, millipedes, and termites.

Muscovy ducks live alone or in groups of 4 to 12, rarely in large flocks. They are mainly active in the morning and afternoon, feeding on the shores of brackish waters, or in the flood savannah and underbrush. They often sleep at night in permanent roosts in trees along the river bank. Heavy and low-flying, they are silent and timid. Muscovy ducks swim much less than other ducks, and the males fly poorly.

We received comments from States and individuals expressing concern over control of muscovy ducks in response to the 2006 proposal to add the species to the list of those protected under the MBTA (50 CFR 10.13). In general, States expressed concern over feral and free-ranging populations of muscovy ducks present as the result of human activity. For example, one State was concerned that protecting the species under the MBTA ''would severely impede our efforts to manage the feral and free-ranging populations of domestic muscovy ducks.'' Individuals expressed concern over property damage and aggressiveness demonstrated by the ducks. The muscovy duck is an introduced species in many locations in the United States. We believe it is prudent to prohibit activities that would allow release of muscovy ducks in areas in which they are not native and may compete with native species.

We expect control of muscovy ducks to be undertaken primarily through the use of walk-in baited traps and through shooting. The use of baited traps will greatly limit the potential impacts to other species, especially passerines, which would be unlikely to enter properly placed traps. Shooting undertaken by State agency or U.S. Department of Agriculture Wildlife Services personnel would be very unlikely to harm other species.

We propose to revise 50 CFR 21.14 to prohibit sale and, in most cases, possession, of muscovy ducks; to revise § 21.25 to prohibit sale or transfer of captive-bred muscovy ducks for hunting; and to add § 21.54 to allow removal of introduced muscovy ducks from any location in the contiguous United States outside Cameron, Hidalgo, Starr, and Zapata Counties in Texas, and in Alaska, Hawaii, and U.S. territories and possessions. This removal is in keeping with the Service's other actions to reduce the spread of introduced species that compete with native species or harm habitats that they use. It also is in keeping with the intent of the Migratory Bird Treaty Reform Act of 2004 (16 U.S.C. 703(b)).

Public Participation

We seek comments on any aspect of this proposed rule. You may submit your comments by either of the methods listed in the **ADDRESSES** section. We will not accept comments sent by email or by fax, or to an address not listed in the **ADDRESSES** section. We will not accept anonymous comments; your comment must include your first and last names, city, state, country, and postal (zip) code. Finally, we will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in the **DATES** section.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* If you provide personal identifying information in addition to the required items specified in the previous paragraph, such as your street address, phone number, or e-mail address, you may request at the top of your document that we withhold this information from public view. However,

we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documents, will be available for public inspection, by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Division of Migratory Bird Management, 4401 North Fairfax Drive, Mail Stop 4107, Arlington, VA 22203–1610.

When submitting written comments, please include your name and return address in your letter and identify it as comments on proposed rule RIN 1018–AV34. To facilitate compiling the administrative record for this action, you must submit written comments on 8½-inch by 11-inch paper.

Required Determinations

Clarity of This Regulation

Executive Order (E.O.) 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this proposed rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections? (A ''section'' appears in bold type and is preceded by the symbol § and a numbered heading; for example: ''§ 21.54 Control order for muscovy ducks in the United States.'') (5) Does the description of the rule in the ''Supplementary Information'' section of the preamble help you to understand the proposed rule? What else could we do to make the rule easier to understand?

Send a copy of any comments that concern how we could make this proposed rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240. You also may e-mail comments to *Exsec@ios.doi.gov.*

Regulatory Planning and Review (Executive Order 12866)

The Office of Management and Budget (OMB) has determined that this rule is not significant and has not reviewed this rule under Executive Order 12866. OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government,

(b) Whether the rule will create inconsistencies with other Federal agencies' actions,

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients, and

(d) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (Pub. L. 104–121)), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule would not have a significant economic impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide the statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities. We have examined this proposed rule's potential effects on small entities as required by the Regulatory Flexibility Act, and have determined that this action would not have a significant economic impact on a substantial number of small entities, because the changes we are proposing are intended primarily to reduce the spread of an invasive species little used in commercial endeavors.

There would very minimal costs, if any, associated with this regulations change. Consequently, we certify that because this proposed rule would not have a significant economic effect on a substantial number of small entities, a regulatory flexibility analysis is not required.

This proposed rule is not a major rule under SBREFA (5 U.S.C. 804(2)). It would not have a significant impact on a substantial number of small entities.

a. This proposed rule would not have an annual effect on the economy of $100 million or more.

b. This proposed rule would not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions.

c. This proposed rule would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we have determined the following:

a. This proposed rule would not ''significantly or uniquely'' affect small governments. A small government agency plan is not required. Actions under the proposed regulation would not affect small government activities in any significant way.

b. This proposed rule would not produce a Federal mandate of $100 million or greater in any year; i.e., it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Takings

In accordance with E.O. 12630, the rule would not have significant takings implications. This proposed rule would not contain a provision for taking of private property. Therefore, a takings implication assessment is not required.

Federalism

This proposed rule would not have sufficient Federalism effects to warrant preparation of a Federalism assessment under E.O. 13132. It would not interfere with the States' ability to manage themselves or their funds. No significant economic impacts are expected to result from control of muscovy ducks.

Civil Justice Reform

In accordance with E.O. 12988, the Office of the Solicitor has determined that the rule would not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

We examined these regulations under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). There are no new information collection requirements associated with this regulations change.

National Environmental Policy Act

We have analyzed this proposed rule in accordance with the National Environmental Policy Act (NEPA), 42 U.S.C. 432–437(f), and part 516 of the U.S. Department of the Interior Manual (516 DM). The change we propose is to allow people and agencies to remove the muscovy duck species from locations in

the United States and United States territories in which the species may have been introduced. We completed an Environmental Action Statement in which we concluded that the proposed regulations change allowing the removal of an introduced species requires no additional assessment of potential environmental impacts.

Environmental Consequences of the Proposed Action

The primary change we propose is to prohibit release of the muscovy duck in locations in which it does not occur naturally. It has been introduced in other locations, where it is an invasive species that sometimes creates problems through competition with native species, damage to property, and transmission of disease. We propose to amend 50 CFR part 21 to prohibit sale of muscovy ducks for hunting, and to allow their removal in locations in which the species does not occur naturally in the contiguous United States, Alaska, and Hawaii, and in U.S. territories and possessions. This would require revisions to § 21.14 (permit exceptions for captive-bred migratory waterfowl other than mallard ducks) and § 21.25 (waterfowl sale and disposal permits), and addition of § 21.54, an order to allow control of muscovy ducks, their nests, and eggs. The first two regulations are to prevent introduction of the species, and have no environmental impact. Because the muscovy duck occurs only in small numbers at scattered locations outside its natural range in southern Texas, the impacts of control of the species under a new regulation at § 21.54 are minimal.

Socioeconomic. This proposed rule would not have discernible socioeconomic impacts.

Migratory bird populations. This proposed rule would not affect migratory bird populations.

Endangered and threatened species. The proposed regulation is for migratory bird species that are not threatened or endangered. It would not affect threatened or endangered species or critical habitats.

Section 7 of the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires that ''The Secretary [of the Interior] shall review other programs administered by him and utilize such programs in furtherance of the purposes of this chapter'' (16 U.S.C. 1536(a)(1)). It further states that the Secretary must ''insure that any action authorized, funded, or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat'' (16 U.S.C. 1536(a)(2)). We have concluded that the proposed regulations change would not affect listed species, and the Division of Migratory Bird Management has conducted an Endangered Species consultation on this proposed rule to confirm this conclusion.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American tribal Governments'' (59 FR 22951), E.O. 13175, and 512 DM 2, we have evaluated potential effects on Federally recognized Indian Tribes and have determined that there are no potential effects. This proposed rule would not interfere with the Tribes' ability to manage themselves or their funds or to regulate migratory bird activities on tribal lands.

Energy Supply, Distribution, or Use (E.O. 13211)

On May 18, 2001, the President issued E.O. 13211 addressing regulations that significantly affect energy supply, distribution, and use. E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Because this proposed rule would affect only import and export of birds in limited circumstances, it is not a significant regulatory action under E.O. 12866, and would not significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

List of Subjects in 50 CFR Part 21

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

For the reasons stated in the preamble, we propose to amend part 21 of subchapter B, chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 21—MIGRATORY BIRD PERMITS

1. The authority for part 21 continues to read as follows:

Authority: Migratory Bird Treaty Act, 40 Stat. 755 (16 U.S.C. 703); Public Law 95–616, 92 Stat. 3112 (16 U.S.C. 712(2)); Public Law 106–108, 113 Stat. 1491, Note following 16 U.S.C. 703.

2. Revise § 21.14 to read as follows:

§ 21.14 Permit exceptions for captive-bred migratory waterfowl other than mallard ducks.

You may acquire captive-bred and properly marked migratory waterfowl of all species other than mallard ducks (*Anas platyrhynchos*), alive or dead, or their eggs, and possess and transport such birds or eggs and any progeny or eggs for your use without a permit, subject to the following conditions and restrictions. Additional restrictions on the acquisition and transfer of muscovy ducks (*Cairina moschata*) are at paragraph (g) of this section.

(a) You may acquire live waterfowl or their eggs only from a holder of a valid waterfowl sale and disposal permit in the United States. You also may lawfully acquire them outside of the United States with appropriate permits (*see* § 21.21 of subpart C of this part).

(b) All progeny of captive-bred birds or eggs from captive-bred birds must be physically marked as set forth in § 21.13(b).

(c) You may not transfer or dispose of captive-bred birds or their eggs, whether alive or dead, to any other person unless you have a waterfowl sale and disposal permit (*see* § 21.25 of subpart C of this part).

(d) Lawfully possessed and properly marked birds may be killed, in any number, at any time or place, by any means except shooting. Such birds may be killed by shooting only in accordance with all applicable hunting regulations governing the taking of like species from the wild (*see* part 20 of this subchapter).

(e) At all times during possession, transportation, and storage until the raw carcasses of such birds are finally processed immediately prior to cooking, smoking, or canning, you must leave the marked foot or wing attached to each carcass, unless the carcass was marked as provided in § 21.25(b)(6) and the foot or wing was removed prior to your acquisition of the carcass.

(f) If you acquire captive-bred waterfowl or their eggs from a waterfowl sale and disposal permittee, you must retain the FWS Form 3–186, Notice of Waterfowl Sale or Transfer, from the permittee for as long as you have the birds, eggs, or progeny of them.

(g) You may not acquire or possess live muscovy ducks, their carcasses or parts, or their eggs, except to raise them to be sold as food. If you possess captive-bred muscovy ducks, you may not propagate them or sell or transfer them to anyone for any purpose, except to be used as food. You may not release them to the wild, including on private property, sell them to be hunted or released to the wild, or transfer them to

anyone to be hunted or released to the wild.

(h) Dealers in meat and game, hotels, restaurants, and boarding houses may serve or sell to their customers the carcass of any bird acquired from a holder of a valid waterfowl sale and disposal permit.

3. Revise § 21.25 to read as follows:

§ 21.25 Waterfowl sale and disposal permits.

(a) *Permit requirement.* You must have a waterfowl sale and disposal permit before you may lawfully sell, trade, donate, or otherwise dispose of, to another person, most species of captive-reared and properly marked migratory waterfowl or their eggs. You do not need a permit to sell or dispose of properly marked captive-reared mallard ducks (*Anas platyrhynchos*) or their eggs.

(b) *Permit conditions.* In addition to the general conditions set forth in part 13 of this subchapter B, waterfowl sale and disposal permits are subject to the following conditions:

(1) You may not take migratory waterfowl or their eggs from the wild, unless take is provided for elsewhere in this subchapter.

(2) You may not acquire migratory waterfowl or their eggs from any person who does not have a valid waterfowl propagation permit.

(3) Before they are 6 weeks of age, all live captive migratory waterfowl possessed under authority of a valid waterfowl sale and disposal permit must be physically marked as defined in § 21.13(b).

(4) All offspring of birds hatched, reared, and retained in captivity also must be marked before they are 6 weeks of age in accordance with § 21.13(b), unless they are held in captivity at a public zoological park, or a public scientific or educational institution.

(5) Properly marked captive-bred birds may be killed, in any number, at any time or place, by any means except shooting. They may be killed by shooting only in accordance with all the applicable hunting regulations governing the taking of like species from the wild.

(6) At all times during possession, transportation, and storage, until the raw carcasses of such birds are finally processed immediately prior to cooking, smoking, or canning, the marked foot or wing must remain attached to each carcass. However, if you have a State license, permit, or authorization that allows you to sell game, you may remove the marked foot or wing from the raw carcasses if the number of your State license, permit, or authorization has been legibly stamped in ink on the back of each carcass and on the wrapping or container in which each carcass is maintained, or if each carcass is identified by a State band on a leg or wing pursuant to requirements of your State license, permit, or authorization.

(7) You may dispose of properly marked live or dead birds or their eggs (except muscovy ducks and their eggs) in any number at any time or place, or transfer them to any person, if the birds are physically marked prior to sale or disposal, regardless of whether or not they have attained 6 weeks of age.

(8) You may propagate muscovy ducks (*Cairina moschata*) only for sale for food.

(i) You may not release muscovy ducks to the wild or transfer them for release to the wild.

(ii) You may not sell or transfer muscovy ducks to be killed by shooting.

(9) If you transfer captive-bred birds or their eggs to another person, you must complete FWS Form 3–186, Notice of Waterfowl Sale or Transfer, and provide all information required on the form, plus the method or methods by which individual birds are marked as required by § 21.13(b).

(i) Give the original of the completed form to the person acquiring the birds or eggs.

(ii) Retain one copy in your files.

(iii) Attach one copy to the shipping container for the birds or eggs, or include it with shipping documents that accompany the shipment.

(iv) By the end of the month in which you complete the transfer, mail two copies to the Fish and Wildlife Service Regional Office that issued your permit.

(c) *Reporting requirements.* You must submit an annual report by January 10th of each year to the Fish and Wildlife Service Regional Office that issued your permit. You must report the number of waterfowl of each species you possess on that date, and the method or methods by which each is marked.

(d) *Applying for a waterfowl propagation permit.* Submit your application for a waterfowl sale and disposal permit to the appropriate Regional Director (Attention: Migratory Bird Permit Office). You can find addresses for the Regional Directors in 50 CFR 2.2. Your application must contain the general information and certification required in § 13.12(a) of subchapter A of this chapter, and the following additional information:

(1) A description of the area where you will keep waterfowl in your possession;

(2) The species and numbers of waterfowl you possess and a statement showing from whom the birds were obtained;

(3) A statement indicating the method by which birds you hold will be marked as required by the provisions of this part 21; and

(4) The number and expiration of your State permit if you are required to have one.

(e) *Term of permit.* A waterfowl sale and disposal permit issued or renewed under this part expires on the date designated on the face of the permit unless amended or revoked, but the term of the permit will not exceed five (5) years from the date of issuance or renewal.

4. Add new § 21.54 to read as follows:

§ 21.54 Control order for muscovy ducks in the United States.

(a) *Control of muscovy ducks.* Anywhere in the contiguous United States except in Cameron, Hidalgo, Starr, and Zapata Counties in Texas, and in Alaska, Hawaii, and U.S. territories and possessions; landowners and Federal, State, and local wildlife management agencies, and their tenants, employees, or agents may, without a Federal permit, remove or destroy muscovy ducks (*Cairina moschata*) or their nests or eggs at any time when found. Any authorized person may temporarily possess, transport, and dispose of muscovy ducks taken under this order.

(b) *Disposal of muscovy ducks.* You may donate muscovy ducks taken under this order to public museums or public institutions for scientific or educational purposes, or you may dispose of them by burying or incinerating them. You may not retain for personal use or consumption, offer for sale, or sell a muscovy duck removed under authority of this section, nor may you release it in any other location.

(c) *Other provisions.* (1) You may not remove or destroy muscovy ducks or their nests or eggs if doing so is contrary to any State, territorial, or tribal laws or regulations.

(2) You may not remove or destroy muscovy ducks or their nests or eggs if doing so will adversely affect other migratory birds or species designated as endangered or threatened under the authority of the Endangered Species Act.

(3) Persons operating under this order must immediately report the take of any species protected under the Endangered Species Act or any other species protected under the Migratory Bird Treaty Act to the Fish and Wildlife Service Ecological Services Office for the State or location in which the take occurred.

(4) We reserve the right to suspend or revoke the authority of any agency or

individual to undertake muscovy duck control if we find that agency or individual has undertaken actions that may harm federally listed threatened or endangered species or are contrary to the provisions of this part.

Dated: August 8, 2008.

David M. Verhey,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E8–19550 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 21

[FWS–R9–MB–2007–0018; 91200–1231–9BPP]

RIN 1018–AV33

Migratory Bird Permits; Control of Purple Swamphens

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose changes in the regulations governing control of depredating or introduced migratory birds. The purple swamphen (*Porphyrio porphyrio*) is not native to any State, and competes with native species. However, we have proposed to add it to the list of species protected under our Migratory Bird Treaty Act obligations because it does occur naturally in American Samoa. We propose to amend 50 CFR part 21 to allow removal of purple swamphens in the contiguous United States, Hawaii, Alaska, Puerto Rico, and the U.S. Virgin Islands.

DATES: We must receive all comments on this proposal by October 21, 2008.

ADDRESSES: You may submit comments, identified as comments on RIN 1018–AV33, by either of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *U.S. Mail or hand delivery:* Public comments Processing, Attention RIN 1018–AV33; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 North Fairfax Drive, Suite 222; Arlington, VA 22203–1610.

We will not accept e-mail or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information that you provide. See the Public Comments section below for more information.

FOR FURTHER INFORMATION CONTACT: Dr. George T. Allen, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 703–358–1825.

SUPPLEMENTARY INFORMATION:

Background

The Fish and Wildlife Service is the Federal agency delegated the primary responsibility for managing migratory birds. This delegation is authorized by the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703 *et seq.*), which implements conventions with Great Britain (for Canada), Mexico, Japan, and the Soviet Union (Russia).

We implement the MBTA through regulations found in title 50 of the Code of Federal Regulations (CFR). In 50 CFR 10.13, we list all species of migratory birds protected by the MBTA that are subject to the regulations protecting migratory birds in title 50, subchapter B (Taking, Possession, Transportation, Sale, Purchase, Barter, Exportation, and Importation of Wildlife and Plants). In 50 CFR part 13 (General Permit Procedures) and part 21 (Migratory Bird Permits), regulations allow us to issue permits for certain activities otherwise prohibited in regard to migratory birds. In part 21, we issue permits for the taking, possession, transportation, sale, purchase, barter, importation, exportation, and banding and marking of migratory birds. We also provide certain exceptions to permit requirements for public, scientific, or educational institutions, and establish depredation and control orders that provide limited exceptions to the MBTA.

Purple Swamphen

The purple swamphen, a chicken-sized bird in the family Rallidae, is native to the Old World, and in the United States and its territories is native only in American Samoa. Because of the species' occurrence in American Samoa, it is protected under the Migratory Bird Treaty Act. We included this species in the proposed rule (71 FR 50194, August 24, 2006) to revise the list of migratory birds found in 50 CFR 10.13. In the United States, the purple swamphen occurs naturally only in the Pacific Island territories of American Samoa, Baker and Howland Islands, Guam, and the Northern Marianas Islands (Pratt et al. 1987). We proposed to add the species to the list because it is in a group of species that belong to families protected under treaties with Canada and Mexico. We anticipate that we will add the species to the list when we finalize the regulation. However, we will not make a final decision on the proposed § 10.13 list before we make a final decision on this purple swamphen proposed rule.

The purple swamphen was introduced in southern Florida through escapes from aviculturalists and from the Miami Metro Zoo in the early 1990s. In Florida, the purple swamphen competes with native species and may impact the plant life of wetlands. The purple swamphen has an international reputation for eating eggs and chicks, including ducklings, of other ground or near-ground nesting species. As far as we know, counties in the southern half of Florida are the only place in the contiguous United States, Hawaii, Alaska, Puerto Rico, or the U.S. Virgin Islands where the purple swamphen occurs.

We propose to allow removal of introduced purple swamphens in the contiguous United States, Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands from any location where they are found. This removal is in keeping with our other actions to reduce the spread of introduced species that compete with native species or harm habitats that they use. It also is in keeping with the intent of the Migratory Bird Treaty Reform Act of 2004 (16 U.S.C. 703(b)).

Public Participation

We seek comments on any aspect of this proposed rule. You may submit your comments by either of the methods listed in the **ADDRESSES** section. We will not accept comments sent by email or by fax, or to an address not listed in the **ADDRESSES** section. We will not accept anonymous comments; your comment must include your first and last names, city, state, country, and postal (zip) code. Finally, we will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in the **DATES** section.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* If you provide personal identifying information in addition to the required items specified in the previous paragraph, such as your street address, phone number, or e-mail address, you may request at the top of your document that we withhold this information from public view. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documents will be available for public inspection, by appointment, during normal business

hours, at the U.S. Fish and Wildlife Service, Division of Migratory Bird Management, 4401 North Fairfax Drive, Mail Stop 4107, Arlington, VA 22203–1610.

When submitting written comments, please include your name and return address in your letter and identify it as comments on proposed regulations change RIN 1018–AV33. To facilitate compiling the administrative record for this action, you must submit written comments on 8½-inch-by-11-inch paper.

Required Determinations

Clarity of This Regulation

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this proposed rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections?) (A ''section'' appears in bold type and is preceded by the symbol ''§'' and a numbered heading; for example: *''§ 21.12 General exceptions to permit requirements.''* (5) Does the description of the rule in the ''Supplementary Information'' section of the preamble help you to understand the proposed rule? What else could we do to make the rule easier to understand?

Send a copy of any comments that concern how we could make this proposed rule easier to understand to the Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240–0001. You also may e-mail comments to *Exsec@ios.doi.gov.*

Regulatory Planning and Review (Executive Order 12866)

The Office of Management and Budget (OMB) has determined that this rule is not significant and has not reviewed this rule under Executive Order 12866. OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government,

(b) Whether the rule will create inconsistencies with other Federal agencies' actions,

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients, and

(d) Whether the rule raises novel legal or policy issues.

Regulatory Planning and Review

In accordance with the criteria in Executive Order 12866, this proposed rule would not be a significant regulatory action. The Office of Management and Budget makes the final determination of significance under E.O. 12866.

a. This proposed rule would not raise novel legal or policy issues. The proposed provisions are in compliance with other laws, policies, and regulations.

b. This proposed rule would not have an annual economic effect of $100 million or more, or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit and economic analysis thus is not required. There would be no costs associated with this proposed rule.

c. This proposed rule would not create inconsistencies with other agencies' actions. The rule deals solely with governance of migratory bird permitting in the United States. No other Federal agency has any role in regulating activities with migratory birds.

d. This proposed rule would not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. There are no entitlements, grants, user fees, or loan programs associated with the regulation of control of purple swamphens.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (Pub. L. 104–121)), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule would not have a significant economic impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide the statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities. We have examined this proposed rule's potential effects on small entities as required by the Regulatory Flexibility Act, and we have determined that this action would not have a significant economic impact on a substantial number of small entities because the changes we are proposing are intended to allow removal of an introduced species that competes with native species of wildlife. Purple swamphens are not found in business areas, and we foresee no effects of this proposed rule on small businesses.

There would be no costs associated with this regulations change. Consequently, we certify that because this proposed rule would not have a significant economic effect on a substantial number of small entities, a regulatory flexibility analysis is not required.

This proposed rule is not a major rule under the SBREFA (5 U.S.C. 804(2)). It would not have a significant impact on a substantial number of small entities.

a. This proposed rule would not have an annual effect on the economy of $100 million or more.

b. This proposed rule would not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions.

c. This proposed rule would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we have determined the following:

a. This proposed rule would not ''significantly or uniquely'' affect small governments. A small government agency plan is not required. Actions under the proposed regulation would not affect small government activities in any significant way.

b. This proposed rule would not produce a Federal mandate of $100 million or greater in any year. It would not be a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Takings

In accordance with Executive Order 12630, the rule would not have significant takings implications. A takings implication assessment is not required. This proposed rule would not

contain a provision for taking of private property.

Federalism

This proposed rule would not have sufficient Federalism effects to warrant preparation of a Federalism assessment under Executive Order 13132. It would not interfere with the States' ability to manage themselves or their funds. No significant economic impacts are expected to result from control of purple swamphens.

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that the rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

We examined these regulations under the Paperwork Reduction Act of 1995. There are no information collection requirements associated with this regulations change.

National Environmental Policy Act

We have analyzed this proposed rule in accordance with the National Environmental Policy Act (NEPA), 42 U.S.C. 432–437(f) and part 516 of the U.S. Department of the Interior Manual (516 DM). The change we propose is to allow people to remove a species from locations in the United States and its territories in which the species may have been introduced. The environmental impacts of control of the purple swamphen have already been addressed. The State of Florida prepared a purple swamphen control plan and a NEPA assessment of State control actions. We completed an Environmental Action Statement in which we concluded that the proposed regulations change allowing the removal of an introduced species requires no additional assessment of potential environmental impacts.

Socioeconomic. We do not expect the proposed action to have discernible socioeconomic impacts.

Migratory bird populations. This proposed rule would not alter the take of native migratory birds from the wild. It would not harm native migratory bird populations.

Endangered and Threatened Species. The purple swamphen is not threatened or endangered, and the proposed regulations change would not affect threatened or endangered species or habitats important to them.

Section 7 of the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires that ''The Secretary [of the Interior] shall review other programs administered by him and utilize such programs in furtherance of the purposes of this chapter'' (16 U.S.C. 1536(a)(1)). It further states that the Secretary must ''insure that any action authorized, funded, or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat'' (16 U.S.C. 1536(a)(2)). We have concluded that the proposed regulations change would not affect listed species, and the Division of Migratory Bird Management has completed an Endangered Species consultation on this proposed rule confirming this conclusion.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and 512 DM 2, we have evaluated potential effects on Federally recognized Indian Tribes and have determined that there are no potential effects. This proposed rule would not interfere with the Tribes' ability to manage themselves or their funds or to regulate migratory bird activities on Tribal lands.

Energy Supply, Distribution, or Use (Executive Order 13211)

On May 18, 2001, the President issued Executive Order 13211 addressing regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Because this proposed rule only affects control of invasive purple swamphens at limited locations, it would not be a significant regulatory action under Executive Order 12866, nor would it significantly affect energy supplies, distribution, or use. This action would not be a significant energy action, and no Statement of Energy Effects is required.

References

Pratt, H. D., P. L. Bruner, and D. G. Berrett. 1987. *The Birds of Hawaii and the Tropical Pacific.* Princeton University Press, Princeton, New Jersey.

List of Subjects in 50 CFR Part 21

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

For the reasons stated in the preamble, we propose to amend part 21 of subchapter B, chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 21—MIGRATORY BIRD PERMITS

1. The authority citation for part 21 continues to read as follows:

Authority: Migratory Bird Treaty Act, 40 Stat. 755 (16 U.S.C. 703); Public Law 95–616, 92 Stat. 3112 (16 U.S.C. 712(2)); Public Law 106–108, 113 Stat. 1491, Note following 16 U.S.C. 703.

2. Add new § 21.53 to read as follows:

21.53 Control order for purple swamphens in the contiguous United States.

(a) *Control of purple swamphens.* Federal, State, Tribal, and local wildlife management agencies, and their tenants, employees, or agents may remove or destroy purple swamphens (*Porphyrio porphyrio*) or their nests or eggs at any time when they find them anywhere in the contiguous United States, Hawaii, Alaska, Puerto Rico, or the U.S. Virgin Islands. Any authorized agency personnel may temporarily possess, transport, and dispose of purple swamphens, subject to the restrictions in paragraph (c) of this section. No permit is necessary to do so.

(b) *Disposal of purple swamphens.* Authorized persons may donate purple swamphens taken under this order to public museums or public institutions for scientific or educational purposes, or they may dispose of the carcasses by burial or incineration. No one may retain for personal use, offer for sale, or sell a purple swamphen removed under this section.

(c) *Other provisions.* (1) Authorized persons may not remove or destroy purple swamphens or their nests or eggs if doing so is contrary to any State, Territorial, Tribal, or local laws or regulations.

(2) Authorized persons may not remove or destroy purple swamphens or their nests or eggs if doing so will adversely affect other migratory birds or species designated as endangered or threatened under the authority of the Endangered Species Act. In particular, the purple swamphen resembles the native purple gallinule (*Porphyrula martinica*). Authorized persons must take special care not to take purple gallinules or their nests or eggs when conducting purple swamphen control activities. Certain persons may take purple gallinules without a permit on rice-producing property in Louisiana according to the terms of a separate depredation order (see § 21.45).

(3) If, while operating under this regulation, an authorized person takes

any other species protected under the Endangered Species Act, the Migratory Bird Treaty Act, or the Bald and Golden Eagle Protection Act, that person must immediately report the take to the nearest Ecological Services office of the Fish and Wildlife Service. See *http://www.fws.gov/where/* to find the location of the nearest Ecological Services office.

(4) We may suspend or revoke the authority of any agency or individual to undertake purple swamphen control if we find that agency or individual has, without an applicable permit, taken actions that may take Federally listed threatened or endangered species or any bird species protected by the Bald and Golden Eagle Protection Act or the Migratory Bird Treaty Act (see § 10.13 of subchapter A of this chapter for the list of protected migratory bird species).

Dated: August 8, 2008.

David M. Verhey,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E8–19552 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 080407531–8569–01]

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: Proposed rule; request for comments.

SUMMARY: The National Marine Fisheries Service (NMFS) proposes to amend 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 will continue, 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. Members of the Bottlenose Dolphin Take Reduction Team (BDTRT) recommended these regulations be 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: Written comments on the proposed rule must be received no later than 5 p.m. eastern time on September 22, 2008.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0648–AW68, by any of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov*.
- Facsimile (fax): 727 824–5309, Attn: Assistant Regional Administrator, Protected Resources.
- Mail: Assistant Regional Administrator for Protected Resources, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701–5505.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

The 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:

BDTRP and Medium Mesh Gillnet Restrictions

Section 118(f)(1) of the Marine Mammal Protection Act (MMPA) requires NMFS to develop and implement take reduction plans to assist in the recovery or prevent the depletion of strategic marine mammal stocks that interact with Category I and II fisheries. The MMPA defines a strategic stock as a marine mammal stock: (1) For which the level of direct human-caused mortality exceeds the potential biological removal (PBR) level; (2) which is declining and likely to be listed under the Endangered Species Act (ESA) in the foreseeable future; or (3) which is listed as threatened or endangered under the ESA or as a depleted species under the MMPA (16 U.S.C. 1362(2)). PBR is the maximum number of animals, not including natural mortalities, that can be removed annually from a stock, while allowing that stock to reach or maintain its optimum sustainable population level. Category I or II fisheries are fisheries that have frequent or occasional incidental mortality and serious injury of marine mammals, respectively.

As specified in the MMPA, the short-term goal of a take reduction plan is to reduce, within six months of its implementation, the incidental mortality or serious injury of marine mammals taken in the course of commercial fishing operations to levels less than PBR for the stock. The long-term goal of a plan is to reduce, within 5 years of its implementation, the incidental mortality or serious injury of marine mammals taken in the course of commercial fishing operations to insignificant levels approaching a zero mortality and serious injury rate, taking into account the economics of the fishery, the availability of existing technology, and existing state or regional fishery management plans. The MMPA also requires NMFS to amend take reduction plans and implementing regulations as necessary to meet the requirements of this section.

On April 26, 2006, NMFS published a final rule (71 FR 24776) implementing the BDTRP, with a May 26, 2006, effective date. The BDTRP contains both regulatory and non-regulatory management measures to reduce serious injury and mortality of the Western North Atlantic coastal bottlenose dolphin stock (dolphin) (*Tursiops truncatus*), a strategic stock, in nine Category I and II commercial fisheries operating within the dolphin's distributional range. The Western North Atlantic coastal bottlenose dolphin stock is split into seven spatial and temporal management units because of its biological complexity, and management measures in the BDTRP are applied by management unit. Both the regulatory and non-regulatory

management measures are designed to meet the BDTRP's short-term goal and provide a framework for meeting the long-term goal.

The regulatory management measures in the BDTRP include seasonal gillnet restrictions, gear proximity requirements, and gear length restrictions. The specific regulatory measures addressed in this proposed rule are nighttime medium mesh (greater than 5–inch (12.7 cm) to less than 7–inch (17.8 cm) stretch) gillnet fishing prohibitions in North Carolina state waters from November 1 through April 30, annually, which will expire on May 26, 2009.

The intent of the medium mesh prohibitions was to address bottlenose dolphin mortalities associated with the spiny dogfish (*Squalus acanthias*) fishery in the North Carolina portion of the Winter-Mixed Management Unit by reducing gillnet soak times. In the winter (November 1 through April 30), three of the seven BDTRP Management Units overlap along the coasts of southern Virginia and North Carolina to form the Winter-Mixed Management Unit. The medium mesh gillnet prohibitions were only implemented in the North Carolina portion of the Winter-Mixed Management Unit because all the observed dolphin mortalities associated with the spiny dogfish fishery occurred in North Carolina state waters.

The medium mesh gillnet restrictions were implemented with an expiration date of May 26, 2009. An expiration date was included for two reasons: (1) Spiny dogfish fishery management plans (FMPs) implemented prior to development of the BDTRP had the unintentional but beneficial effect of reducing serious injury and mortality of dolphins; however, the BDTRT recognized that any future changes to the FMPs may reduce or reverse these benefits; and (2) to provide assurance that the BDTRT would regularly review the status of the dynamic spiny dogfish fishery and any implications on dolphin bycatch estimates should a directed fishery reemerge, especially in North Carolina.

Spiny Dogfish Fishery Management Plans and the North Carolina Fishery

The spiny dogfish fishery is actively managed by FMPs in both Federal and state waters. NMFS listed spiny dogfish as overfished in 1998 (63 FR 17820, April 10, 1998). In January 2000, a Federal FMP (65 FR 1557, January 11, 2000) was issued by NMFS to conserve spiny dogfish in Federal waters. Among other things, the FMP implemented a coastwide commercial quota that is specified annually and split into two seasonal fishing periods (Period 1: May 1 to October 31; Period 2: November 1 to April 30). Each fishing period also has separate possession trip limits, specified annually, to allow for bycaught spiny dogfish to be sold while preventing a directed fishery (63 FR 17820, April 10, 1998; ASFMC, 2007a).

The Atlantic States Marine Fisheries Commission (ASMFC) issued an emergency action in 2000 requiring states to mirror Federal closures in state waters. An Interstate FMP was developed in November 2002 to manage spiny dogfish fishing in state waters and implemented in the 2003/2004 fishing year. The Interstate FMP largely mirrors the Federal FMP, setting annual commercial quotas and separate possession limits for the same two fishing periods (ASFMC, 2007a). All commercial landings count toward the interstate FMP quota regardless of where the fish are caught (i.e., state or Federal waters) (ASFMC, 2002).

The specification of commercial quotas, established annually and split semi-annually, is intended to provide each state with an opportunity to land low levels of spiny dogfish bycatch, while helping achieve healthy and self-sustaining populations. Because of the species' annual migratory pattern along the United State's east coast, however, quota overages often occur in the northern states associated with harvest Period 1. These overages result in reduced or restricted harvest for southern states in Period 2 (ASFMC, 2002). For example, when the fishery was still active in North Carolina state waters, peak harvests occurred during February and March, corresponding to harvest Period 2. However, as a result of the semi-annual quotas, there has not been a directed spiny dogfish fishery since the FMPs' implementation, with the exception of 2003/2004 when a state-by-state quota was established for state waters allowing a small-scale directed fishery (NCDMF, 2008).

Following implementation of the FMPs, the directed spiny dogfish fishery in North Carolina was virtually eliminated, as seen by low spiny dogfish landings and reduced soak times. Spiny dogfish landings averaged 6,703,985 pounds from 1995 to 2000, which was 16.9 percent of the coastwide commercial landings. From 2000 to 2006, after implementation of the FMPs, landings in North Carolina averaged 92,169 pounds, representing 4.6 percent of the coastwide commercial landings (NMFS, Fisheries Statistic Division, pers. comm.). Observer data also indicate that soak times changed because of the low trip limits for the fishery; the average soak time decreased from 13.5 hours (1996–2000) to 1.5 hours (2001–2006).

Dolphin Mortalities Associated with the Spiny Dogfish Fishery

The implementation of the spiny dogfish FMPs and subsequent effort reductions had the inadvertent but beneficial effect of reducing dolphin serious injuries and mortalities. From 1996 to 2000 in the North Carolina portion of the Winter-Mixed Management Unit, the medium mesh spiny dogfish fishery was the primary contributor to total dolphin mortality (Rossman and Palka, 2004). The mean annual mortality estimate for the Winter-Mixed Management Unit from 1996 to 2000 was 180, which exceeded the PBR of 68 (NMFS, 2007; Rossman and Palka, 2004). Sixty-three percent, or 146 of the 180 dolphin serious injuries and mortalities, were attributed to the North Carolina portion of the Winter-Mixed Management Unit. Conversely, from 2001 to 2002 in the Winter-Mixed Management Unit, small (less than or equal to 5–inch (12.7 cm) stretched) and large (greater than or equal to 7–inch (17.8 cm) stretched) mesh gillnets were the primary contributors to total dolphin serious injury and mortality. During 2000 to 2001, mean annual estimated dolphin mortality decreased to 59 dolphins, of which, only 19, or 24 percent, were attributed to the North Carolina portion of the Winter-Mixed Management Unit. This reduction in estimated dolphin mortality was a result of reduced landings and lower bycatch rates across all mesh size categories, including the North Carolina spiny dogfish fishery following implementation of the FMPs (Rossman and Palka, 2004).

Recent declines in winter dolphin standings in North Carolina support this trend. Byrd et al. (2008) compared the number of dolphins that stranded in North Carolina with conclusive signs of a fishery interaction during the winter from November 1997 through April 2005 and found a significant decrease in dolphin strandings after the FMPs were implemented. Updated stranding data for winter 2005/2006 and 2006/2007 showed continued decreases in dolphin strandings, with no more than one dolphin per winter stranding with signs of fishery interactions (Lovewell and Byrd, 2007).

When the BDTRT deliberated in 2002 and 2003 on their consensus recommendations for a draft BDTRP, they recognized the inadvertent benefit the spiny dogfish FMPs had in reducing dolphin serious injuries and mortalities incidental to this fishery. However, the

dual-nature by which the spiny dogfish fishery is managed both state and federal entities, coupled with the potential for the FMPs to change as the fish population rebuilds, results in a process that is dynamic and unreliable for dolphin conservation. Therefore, the BDTRT recommended the nighttime medium mesh gillnet prohibitions in the North Carolina portion of the Winter-Mixed Management Unit be included in the BDTRP to provide continued dolphin conservation. The BDTRT also recommended an expiration date on the prohibition to ensure regular review of the fishery should the fishery dynamics change.

The prohibition was included in the BDTRP because it was anticipated to maintain the recently reduced dolphin mortality within the spiny dogfish fishery. The nighttime medium mesh gillnet fishing prohibitions are important for dolphin conservation because they limit soak times to approximately 12 hours. Before implementation of the FMPs, long soak durations associated with the spiny dogfish fishery were likely a contributing factor to the fishery's high dolphin bycatch rate. Observer data prior to the FMPs' implementation document three mortalities in medium mesh spiny dogfish nets with soak times greater than 12 hours and only one mortality with a soak time of less than 12 hours. Soak times were significantly decreased following the implementation of the FMPs, and since 2000, there have been no observed takes associated with the fishery. Nighttime fishing in the medium mesh gillnet fishery was prohibited under the BDTRP to prevent a return to the fishery's pre-FMP fishing practices (i.e., long soak times) should spiny dogfish quotas be increased or reallocated, resulting in a directed fishery in North Carolina (Rossman and Palka, 2004).

Recent Developments in the Spiny Dogfish Fishery

The 2006 estimate of fishing mortality for spiny dogfish indicated the population was not overfished and overfishing was not occurring (NMFS, 2006). Both FMPs are reviewed annually based on the most recent estimate of spiny dogfish fishing mortality. ASMFC modified their quotas and trips limits for the 2006/2007 fishing year based on the 2006 estimate of fishing mortality; however, the Federal specifications were unchanged. This was the first time since 2002 that the coastwide commercial quota was established at different levels for the state and Federal FMPs. Specifically, for the 2006/2007 fishing year, the Federal FMP quota remained at 4 million pounds with 600 pound state possession limits to discourage a directed fishery (71 FR 40436, July 17, 2006). However, the interstate FMP specifications were modified by increasing the quota from 4 to 6 million pounds with 600 pound state possession limits (ASMFC, 2007a). This left two million pounds for harvest in state waters once the Federal waters were closed. No changes were made for the 2007/2008 fishing year for either FMP. For the 2008/2009 fishing year, the state water quota increased to eight million pounds with possession trip limits up to 3,000 pounds (ASMFC, 2007b); the federal water quota and possession limits remained unchanged (71 FR 40436, July 17, 2006). As the spiny dogfish population rebuilds, it is anticipated that the quotas will continue to be increased accordingly.

Despite the recent increase in quotas, the spiny dogfish fishery in North Carolina is still almost nonexistent, as evidenced by the continued low landings. The following major factors contribute to preventing a viable spiny dogfish fishery in North Carolina:

(1) The total available FMP quotas are separated according to season and, thus, region. Although this management scheme is intended to allocate available fishery resources in a biologically sustainable manner that is equitable to all fishermen, it is difficult to assign quota overages on a state level because of the seasonal and regional quota separation. Specifically, the fishing year beginning on May 1 provides more opportunity for the northern states to intercept spiny dogfish before their seasonal migration south. Therefore, northern states generally land both the entire Federal and ASMFC quotas before the spiny dogfish migrate south to North Carolina (NCDMF, 2008), resulting in Period 2 fishery closures in November and December (66 FR 58074, November 20, 2001; 67 FR 70027, November 20, 2002; 71 FR 76222, December 20, 2006; 72 FR 64952, November 19, 2007);

(2) Following the implementation of the FMPs, the mid-Atlantic processors closed, leaving only two processors in New England (ASFMC, 2002). At times, the processing plants are saturated with spiny dogfish harvested from states north of North Carolina. Therefore, when spiny dogfish arrive in North Carolina waters, there is no market to harvest and process the fish; and

(3) If a portion of the quota were available when spiny dogfish arrive in North Carolina waters, the current possession trip limit of 600 pounds in federal waters or even 3,000 pounds in state waters may still not allow for a directed spiny dogfish fishery. North Carolina fishermen indicated that trip limits of at least 4,000 pounds would be necessary to make the fishery feasible (NCDMF, 2008). In a predominantly bycatch fishery, it is not cost effective for fishermen or dealers to truck spiny dogfish to the processors in New England, given high fuel costs and the small amount of fish permitted to be harvested per trip.

These factors may continue to prevent a directed spiny dogfish fishery in North Carolina, despite the recent increases in the coastwide commercial quota. However, the North Carolina Department of Marine Fisheries (NCDMF) believes state-by-state quotas under the interstate FMP would allow a more equitable allocation of the quota and quota overage or transfer provisions (NCDMF, 2008). ASMFC will consider a state-by-state allocation approach during its August 2008 meeting. If state-by-state quotas are considered and adopted by ASMFC and quotas and trip limits continue to increase, a directed spiny dogfish fishery in North Carolina may emerge in the future.

Bottlenose Dolphin Take Reduction Team Recommendations

The BDTRT met on June 19–20, 2007, in Annapolis, Maryland for the first time since the BDTRP's implementation. The purpose of this meeting was to monitor the effectiveness of the BDTRP and discuss potential modifications to any measures that may not be reducing dolphin serious injuries and mortalities. Among other things, the BDTRT was provided with updates on the spiny dogfish fishery, its quotas under both FMPs, and spiny dogfish landings and gear practices for the past five years.

The BDTRT recommended by consensus that the nighttime medium mesh gillnet prohibitions in the Winter-Mixed Management Unit for North Carolina be extended for an additional three years, with an update on the status of the spiny dogfish fishery provided to the team at least every two years. The BDTRT agreed it is important that the BDTRP medium mesh regulations remain in place because of the historically high dolphin bycatch rates in the medium mesh spiny dogfish fishery and the uncertainty in the fishery and fishing status. Extending the medium mesh prohibition timeframe for another three years, rather than removing the expiration date entirely, also ensures the BDTRT will periodically review the status of the spiny dogfish fishery and recommend revisions to the BDTRP, as necessary. NMFS agrees extending the prohibitions is necessary to ensure continued conservation of dolphins due to high

serious injury and mortality rates associated with past spiny dogfish fishery practices and potential future changes in the FMPs. NMFS also agrees extending these prohibitions until 2012 is necessary to ensure the BDTRT continues to reexamine the spiny dogfish fishery and determine if these requirements are still required or sufficient given the dynamic nature of the fishery and its management.

Classification

This proposed rule has been determined to be not significant under Executive Order 12866.

NMFS determined this action is consistent to the maximum extent practicable with the enforceable policies of the approved coastal management program of North Carolina. This determination was submitted for review by the responsible state agencies under section 307 of the Coastal Zone Management Act.

This action contains policies with federalism implications that were sufficient to warrant preparation of a federalism summary impact statement under Executive Order 13132 and a federalism consultation with officials in the state of North Carolina. Accordingly, the Assistant Secretary for Legislative and Intergovernmental Affairs provided notice of the proposed action to the appropriate officials in North Carolina.

NMFS determined this action is categorically excluded from the requirement to prepare an Environmental Assessment in accordance with sections 5.05b and 6.03c.3(i) of NOAA's Administrative Order (NAO) 216–6. Specifically, this proposed action extends the timeframe of a current regulation that, if implemented, would not substantially change the regulation or have a significant impact on the environment. NMFS prepared an Environmental Assessment (EA) on the final rule (71 FR 24776, April 19, 2006) to implement the BDTRP, which included an analysis of the proposed action without time constraints. The EA analyzed all regulations in the final BDTRP of which the regulations addressed in this proposed action were a component. The EA resulted in a finding of no significant impact. In accordance with section 5.05b of the NAO, the proposed regulations were determined to not likely result in significant impacts as defined in 40 CFR 1508.27. This action does not trigger the exceptions to categorical exclusions listed in NAO 216–6, Section 5.05c. A categorical exclusion memorandum to the file has been prepared.

An ESA section 7 consultation was conducted on this action and found that it may affect, but is not likely to adversely affect, threatened and endangered species or adversely modify designated critical habitat under NMFS' jurisdiction. NMFS expects this action to be beneficial to listed species because it will maintain reduced soak times in medium mesh gillnet fishing in North Carolina state waters.

This proposed rule does not contain collection-of-information requirements subject to the Paperwork Reduction Act.

As required by section 603 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), an initial regulatory flexibility analysis (IRFA) was prepared, which is based on the Environmental Assessment, Regulatory Impact Review, and Final Regulatory Flexibility Act Analysis for the BDTRP, dated April 2006. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are included in the preamble of this proposed rule. A summary of the analysis follows.

The purpose of this proposed rule is to reduce serious injuries and mortalities to bottlenose dolphins incidental to commercial fishing operations and ensure serious injuries and mortalities do not exceed PBR levels, as mandated by the MMPA. The specific objectives of this proposed action are to: (1) meet the BDTRP's short- and long-term objectives by maintaining reductions in serious injuries and moralities of dolphins associated with the medium mesh spiny dogfish fishery in North Carolina state waters; and (2) ensure the BDTRT is provided with continued opportunities to review the status of the dynamic spiny dogfish fishery and recommend revisions to the BDTRP, as necessary. These objectives are expected to be accomplished by continuing reduced soak times in medium mesh gillnet gear in North Carolina via the seasonal, nighttime medium mesh gear prohibitions for an additional three years. The MMPA provides the statutory basis for the proposed rule.

No duplicative, overlapping, or conflicting Federal rules have been identified.

The proposed rule will not impose any additional reporting, recordkeeping, or compliance requirements. The compliance requirements of the proposed rule are as described in this anaylsis.

A total of 1,321 unique participants were identified as having recorded landings using medium mesh gillnet gear during the 2001 fishing season (November 2000 - October 2001) in North Carolina. Total harvests with this gear were valued at approximately $13.8 million (nominal ex-vessel value), or approximately 18 percent of total fishing revenues by these entities of approximately $77 million (nominal ex-vessel value). The average annual revenue from the harvest of all marine species by these vessels was approximately $58,000.

A business involved in fish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $4.0 million (NAICS code 114111, finfish fishing) for all its affiliated operations worldwide. All medium mesh gillnet commercial fishing operating in the manner and location encompassed by the proposed action would be affected by the proposed rule. The available estimate of the average annual revenues by vessels operating in the medium mesh gillnet commercial fisheries in North Carolina provided above ($58,000) is from the 2001 fishing season. Since that time, as a result of the implementation of the FMP, spiny dogfish fishery revenues have decreased. Therefore, we determined that all entities affected by the proposed rule are small businesses.

All business entities participating in the medium mesh gillnet fishery in North Carolina are considered small entities; therefore, the issue of disproportional impacts between large and small entities as a result of the proposed action does not arise.

Information on the current profit profile of participants in the North Carolina medium mesh gillnet fishery is not available. Inferences on the effects of the proposed rule on profitability of the impacted small entities, however, may be drawn from examination of the expected impacts on ex-vessel revenues. In 2001, total costs associated with harvest reductions (lost ex-vessel revenue) for the medium mesh gillnet fisheries in North Carolina during the winter were estimated to be approximately $296,000 for the initial implementation of the prohibition in the BDTRP. This reduction in ex-vessel revenues represented less than 1 percent of total ex-vessel revenues for the entities that used this gear in North Carolina during the winter for the 2001 fishing year. Updated analyses are not available. Spiny dogfish were the primary target of the medium mesh gillnet sector, and the spiny dogfish fishery was essentially eliminated in 2000 through FMP actions. Since then,

there has not been a large-scale directed fishery for this species in North Carolina. This prevents the meaningful quantification of current revenues that might be foregone as a result of the proposed action, as well as the identification and description of fishing entities that might desire to re-enter the fishery should the fishery reemerge in North Carolina in the future.

It should be emphasized that the proposed action would not directly affect any current fishing revenues or fishing practices because the medium mesh spiny dogfish gillnet fishery in North Carolina has not operated since the May 26, 2006, implementation of the BDTRP, nor in any substantive manner since 2000. Instead, the proposed continuation of the nighttime fishing prohibition would have an effect only if a directed spiny dogfish fishery reemerges in North Carolina because of changes in FMP actions. In that case, the proposed action would reduce potential medium mesh gillnet fishing opportunities by limiting soak times, and would limit the redevelopment and prosecution of a fishery that, prior to the FMPs and BDTRP, contributed a relatively minor share of fishing revenues to the fishery participants.

NMFS considered two alternatives for the proposed action. The first alternative, the status quo, would continue current restrictions until May 26, 2009, when the medium mesh gillnet prohibitions in North Carolina would expire. This alternative would allow increased soak times associated with the directed spiny dogfish fishery and associated revenues, if FMP actions allow for the reemergence of a directed fishery in North Carolina. However, this alternative would not prevent future incidental mortality and serious injury to dolphins from extended soak time of medium mesh commercial gillnet gear, and, therefore, would not meet the objectives of the BDTRP. The second alternative, the proposed action, would continue, without modification, current nighttime medium mesh gillnet restrictions in North Carolina state waters during the winter for an additional three years (until May 26, 2012). This alternative is a consensus recommendation of the BDTRT and would achieve the BDTRP's objectives, as mandated by the MMPA, by continuing to reduce serious injuries and mortalities of dolphins incidental to commercial gillnet fishing.

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List of Subjects in 50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

Dated: August 18, 2008.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 229 is proposed to be amended as follows:

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

1. The authority citation for part 229 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*; § 220.32(f) also issued under 16 U.S.C. 1531 *et seq.*

2. In § 229.35 paragraphs (d)(4)(ii) and (d)(5)(i) are revised to read as follows:

§ 229.35 Bottlenose Dolphin Take Reduction Plan.

* * * * *

(d) * * *

(4) * * *

(ii) *Medium mesh gillnets.* From November 1 through April 30 of the following year, in Northern North Carolina State waters, no person may fish with any medium mesh gillnet at night. This provision expires on May 26, 2012.

* * * * *

(5) * * *

(i) *Medium Mesh Gillnets.* From November 1 through April 30 of the following year, in Southern North Carolina State waters, no person may fish with any medium mesh gillnet at night. This provision expires on May 26, 2012.

* * * * *

[FR Doc. E8–19580 Filed 8–21–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 070719388–81094–02]

RIN 0648–AV29

Fisheries in the Western Pacific; Crustacean Fisheries; Deepwater Shrimp

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

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed rule would designate deepwater shrimp of the genus *Heterocarpus* as management unit species (MUS), and require Federal permits and data reporting for deepwater shrimp fishing in Federal waters of the western Pacific. The proposed rule is intended to improve information on deepwater shrimp

fisheries and their ecosystem impacts, and to provide a basis for future management of the fisheries, if needed.

DATES: Comments on the proposed rule must be received by October 6, 2008.

ADDRESSES: Comments on this proposed rule, identified by 0648–AV29, may be sent to either of the following addresses:

- Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov*; or
- Mail: William L. Robinson, Regional Administrator, NMFS, Pacific Islands Region (PIR), 1601 Kapiolani Blvd, Suite 1110, Honolulu, HI 96814–4700.

Instructions: All comments received are a part of the public record and will generally be posted to *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the commenter may be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''NA'' in the required name and organization fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the Fishery Management Plan for Crustacean Fisheries of the Western Pacific Region (FMP), and proposed FMP Amendment 13, which includes an environmental assessment (EA), are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or *www.wpcouncil.org*.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to William L. Robinson, and by e-mail to *David__Rostker@omb.eop.gov* or fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Brett Wiedoff, NMFS PIR, 808–944–2272.

SUPPLEMENTARY INFORMATION: This **Federal Register** document is accessible at the Office of the **Federal Register** website: *www.gpoaccess.gov/fr*.

Crustacean fisheries in the western Pacific are federally-managed within the waters of the U.S. Exclusive Economic Zone (EEZ) around American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), Guam, Hawaii, and the Pacific Remote Island Areas (PRIA, comprising Palmyra Atoll, Kingman Reef, Jarvis Island, Baker Island, Howland Island, Johnston Atoll, Wake Island, and Midway Atoll). The EEZ around the CNMI and PRIA extends from the shoreline seaward to 200 nautical miles (nm), and the EEZ around the other islands extends from three to 200 nm offshore. Currently, the crustaceans FMP management unit species include the spiny lobsters *Panulirus marginatus* and *P. penicillatus*, slipper lobsters of the family Scyllaridae, and Kona (spanner) crab, *Ranina ranina*.

Eight species of the deepwater shrimp genus *Heterocarpus* have been reported throughout the tropical Pacific, generally at depths of 200 to 1,200 meters on the outer reef slopes that surround islands and deepwater banks. Species distribution tends to be stratified by depth with some overlap. The deepwater trap fisheries have primarily targeted *Heterocarpus ensifer* and *H. laevigatus*.

Western Pacific commercial trap fisheries for deepwater shrimp are intermittent. There have been sporadic operations in Hawaii since the 1960s, small-scale fisheries in Guam during the 1970s, and some activity in the CNMI during the mid–1990s. The fisheries have been unregulated, and there has been no comprehensive collection of information about the fisheries. Most of these fishing ventures have been short-lived, probably as a result of sometimes-frequent loss of traps, a shrimp product with a short shelf life and history of inconsistent quality, and the rapid localized depletion of deepwater shrimp stocks leading to low catch rates. Despite these hurdles, interest in deepwater shrimp fisheries continues.

Amendment 13 would designate deepwater shrimp of the genus *Heterocarpus* as management unit species under the FMP, and would require Federal permits and reporting for deepwater shrimp fishing in the U.S. EEZ. The proposed monitoring program (permits and logbooks) is intended to improve understanding of these fisheries and their impact on marine ecosystems. Although currently there are no resource concerns regarding western Pacific deepwater shrimp, the proposed designation of these shrimp as management unit species would provide a basis for management of the fisheries, if warranted in the future.

In addition to the proposed rule, Amendment 13 designates Essential Fish Habitat (EFH) for *Heterocarpus* spp. as required under the Magnuson-Stevens Act. To reduce the complexity and the number of EFH identifications required for each individual species and life stages of the genus Heterocarpus in the western Pacific, EFH has been designated for the complete assemblage of adult and juvenile *Heterocarpus* spp. as the outer reef slopes between 300 and 700 meters surrounding every island and submerged banks in the western Pacific. The species complex designations includes all eight species of deepwater shrimp extant in the western Pacific (*Heterocarpus ensifer*, *H. laevigatus*, *H. sibogae*, *H. gibbosus*, *H. Lepidus*, *H. dorsalis*, *H. tricarinatus* and *H. longirostris*).

In addition to adding deepwater shrimp to the management unit, this proposed rule would reorganize some existing regulations relating to the Northwestern Hawaiian Islands (NWHI) lobster limited access permit program. These regulations, now in paragraphs § 665.41(a)(1), (a)(3), (a)(4), and 665.41(d), would be consolidated into paragraph § 665.41(d). The regulations would also clarify that the harvest of crustacean management unit species within the NWHI Marine National Monument is subject to the requirements of 50 CFR part 404.

To be considered, comments must be received by close of business on October 6, 2008, not postmarked or otherwise transmitted by that date.

In addition to soliciting public comments on this proposed rule, NMFS is soliciting comments on proposed FMP Amendment 13 through October 14, 2008 as stated in the Notice of Availability published on August 14, 2008 (50 CFR Part 665). Public comments on this proposed rule, if received by October 14, 2008, will also be considered in the approval/disapproval decision for Amendment 13. Comments received after that date will not be considered in the approval/disapproval decision for Amendment 13, but will be considered for this proposed rule.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Crustaceans FMP, other provisions of the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

Amendment 13 includes an EA that discusses the impacts on the environment as a result of this rule. The purpose and need for the proposed action is to establish appropriate monitoring and management mechanisms for the domestic harvest of western Pacific deepwater shrimp. Based on the information in the EA, as

compared to the no-action alternative, the preferred alternative would have no adverse impacts to essential fish habitat or habitat areas of particular concern. None of the action alternatives would be expected to change the impacts of U.S. vessels on deepwater shrimp resources in the short term, but impacts on the resource base could increase with higher future effort, so increasing fishery managers' understanding of the status of the stocks and fishing mortality would be an important outcome of this action. By including deepwater shrimp as management unit species, the foundation would be established for implementing control measures, should they become necessary. None of the action alternatives is anticipated to have any significant adverse impacts on seabird, sea turtle, or marine mammal populations because the fishery has a relatively low level of participation, and there have been no observed or reported interactions with protected resources in the deepwater shrimp fishery. The preferred alternative would provide for the sustained participation of fishing communities by helping to ensure the long-term availability of western Pacific deepwater shrimp. The complete analysis of the alternatives is contained in Amendment 13, including an EA, and is not repeated here. Copies of the environmental analytical documents is available from the Council (see **ADDRESSES**).

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Council for Regulation of the Department of Commerce certified to the Chief Council for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

A description of the action, why it is being considered, and the legal basis for this action are contained in the preamble to the proposed rule. This rule does not duplicate, overlap, or conflict with other Federal rules. There are no disproportionate economic impacts from this rule based on home port, gear type, or relative vessel size. Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. § 605(b), the NMFS Pacific Islands Regional Office has determined that this rule will not have a significant economic impact on a substantial number of small entities based on the pre-existing status of deepwater shrimp fisheries within the U.S. EEZ of the western Pacific. All vessels having the potential to participate in this fishery are considered to be small entities under the current Small Business Administration definition of small fish-harvesting businesses (gross receipts not in excess of $ 4.0 million, independently owned and operated, and not dominant in the field). While fishing for deepwater shrimp has been sporadic over the last several decades, in 1984, a total of 17 vessels reported catching approximately 159 tons of deepwater shrimp worth an estimated ex-vessel value of $780,000. More recent information is not possible because confidentiality rules restrict the release of information from the small number of participants.

Alternative 1 (no action) would preclude Federal monitoring and management of known deepwater shrimp fisheries operating within the western Pacific. Alternative 2 would include deepwater shrimp as management unit species (MUS) under the Crustaceans FMP, enabling the Council and NMFS to develop management measures, as appropriate, for deepwater shrimp fisheries in the region. Alternative 3 would add deepwater shrimp to the MUS, as in Alternative 2, and would also require Federal permitting and reporting of harvest for vessels engaged in the deepwater shrimp fishery.

Alternatives 1 and 2 would yield no economic impact to small entities (vessels). However, Alternative 3 would have a slightly adverse economic impact resulting in a requirement to pay a vessel permit fee of approximately $30. Applied on a 1984 dollar base, this represents only 0.06 percent of the average boat revenue for 1984. Alternative 3 represents the most adverse economic impact of the 3 alternatives. However, the fishery cannot be monitored and managed under the requirements of the Magnuson-Stevens Act, particularly National Standards 1 and 2, without accurate and reliable data on shrimp effort and production associated with required permitting, recordkeeping and reporting from the directed deepwater shrimp.

As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval. The preferred alternative would require the owners of U.S. vessels that fish for deepwater shrimp management unit species in the western Pacific to obtain Federal fishing permits, and the vessel operators would be required to complete and submit Federal catch reports. Permit eligibility would not be restricted in any way, and the permit would be renewable on an annual basis.

NMFS anticipates that initial permit applications would require 0.5 hours per applicant, with renewals requiring an additional 0.5 hours annually. It is estimated that NMFS may receive and process up to 10 permit applications each year. Thus, the total collection-of-information burden to fishermen for permit applications is estimated at five (5) hours per year. The cost for individual Federal permits has not been determined, but would represent only the administrative cost and is anticipated to be approximately $30 per permit.

NMFS anticipates the time requirement to complete Federal catch reports to be approximately 10 minutes per vessel per fishing day. Assuming that 10 vessels fish during up to 100 days per year, the total collection-of-information burden estimate for fishing data reporting is estimated at 167 hours per year.

Public comment is sought regarding: whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to William L. Robinson (see **ADDRESSES**), and by e-mail to *David_Rostker@omb.eop.gov* or fax to 202–395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

List of Subjects in 50 CFR Part 665

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Guam, Hawaii, Hawaiian Natives, Northern Mariana Islands, Pacific remote island areas, Reporting and recordkeeping requirements.

Dated: August 18, 2008.

Samuel D. Rauch III,

Deputy Assistant Administrator For Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 665 is proposed to be amended as follows:

PART 665—FISHERIES IN THE WESTERN PACIFIC

1. The authority citation for 50 CFR part 665 continues to read as follows:

Authority: 16 U.S.C. 1801 et seq.

2. In § 665.12, revise the definition of ''Crustaceans management unit species'' to read as follows:

§ 665.12 Definitions.

* * * * *

Crustaceans management unit species means the following crustaceans:

Common Name	Scientific Name
Spiny lobsters	Panulirus marginatus
	P. penicillatus
Slipper lobsters	family Scyllaridae
Kona crab	Ranina ranina
Deepwater shrimp	Heterocarpus spp.

* * * * *

3. In § 665.13, revise paragraphs (f)(2)(i) through (f)(2)(v), and add a new paragraph (f)(2)(vi) to read as follows:

§ 665.13 Permits and fees.

* * * * *

(f) Fees. * * *

(2) * * *

(i) Hawaii longline limited access permit.

(ii) Mau Zone limited access permit.

(iii) Coral reef ecosystem special permit.

(iv) American Samoa longline limited access permit.

(v) Main Hawaiian Islands non-commercial bottomfish permit.

(vi) Crustaceans permit.

* * * * *

4. In § 665.41, revise paragraphs (a) and (d) to read as follows:

§ 665.41 Permits.

(a) Applicability. (1) The owner of any vessel used to fish for lobster in Crustaceans Permit Area 1 must have a lobster limited access permit issued for such vessel.

(2) The owner of any vessel used to fish for lobster in Crustaceans Permit Areas 2, 3, or 4 must have a permit issued for that vessel.

(3) The owner of any vessel used to fish for deepwater shrimp in Crustaceans Permit Areas 1, 2, 3, or 4 must have a permit issued for that vessel.

(4) Harvest of crustacean management unit species within the Northwestern Hawaiian Islands Marine National Monument is subject to the requirements of 50 CFR part 404.

* * * * *

(d) Lobster Limited Access Permit Requirements.

(1) A lobster limited access permit is valid for fishing only in Crustaceans Permit Area 1.

(2) Only one permit will be assigned to any vessel.

(3) No vessel owner will have permits for a single vessel to harvest lobsters in Permit Areas 1 and 2 at the same time.

(4) A maximum of 15 limited access permits can be valid at any time.

* * * * *

5. In § 665.42, add a new paragraph (c) to read as follows.

§ 665.42 Prohibitions.

* * * * *

(c) In any Crustaceans Permit Area, it is unlawful for any person to:

(1) Fish for, take, or retain deepwater shrimp without a permit issued under § 665.41.

(2) Falsify or fail to make, keep, maintain, or submit Federal reports and records of harvests of deepwater shrimp as required under § 665.14.

[FR Doc. E8–19579 Filed 8–21–08; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 73, No. 164
Friday, August 22, 2008

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Assistant Secretary for Civil Rights; Notice of Request for Emergency Approval of New Information Collection, Paper Reduction Act of 1995

AGENCY: Office of the Assistant Secretary for Civil Rights, USDA/1890 Programs.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Office of the Assistant Secretary for Civil Rights, USDA/1890 Program intention to request an emergency approval of information collection for the USDA/1890 National Scholars Program.

DATES: Comments on this notice must be received to be assured of consideration.

Additional Information or Comments: Contact Carl Butler, USDA/1890 National Scholars Program Manager, U.S. Department of Agriculture, 300 7th Street, SW., Suite 266, Room 273, Washington, DC 20024 (202) 205–2641 (Fax number).

SUPPLEMENTARY INFORMATION: Overview of the information collected.

Title: USDA/1890 National Scholars Program Application.

Type of Request: Emergency approval of new information collection.

Abstract: The USDA/1890 National Scholars Program is a joint human capital initiative between the U.S. Department of Agriculture (USDA) and Historical Black Land-Grant Universities. Through the Program, USDA offers scholarships to high school students who are seeking a bachelor's degree, in the fields of agriculture, food, or natural resource sciences and related majors, at one of the eighteen Historically Black Land-Grant Universities. In order for graduating high school students to be considered for the scholarship, a completed application is required. The first section of the application requests the applicant to include biographical information (e.g., name, address, age, etc.); educational background information (e.g., grade point average, test scores, name of university(ies) interested in attending, and desired major); and extracurricular activities. The second of the application section is completed by the student's guidance counselor and requests information pertaining to the student's academic status, grade point average, and test scores. The last section of the application, which is to be completed by a teacher, provides information that assesses the applicant's interest, habits, and potential. All of this information is used to assist the selecting agencies in their process of identifying potential recipients of the scholarship.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1 hour per respondent.

Respondents: High school students, teachers, guidance counselors (each application requires 3 respondents to complete a section).

Estimated Number of Respondents: 1,200 (400 applications).

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 3,600 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the agency's functions, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Carl Butler, 300 7th Street, SW., Reporter's Building, Suite 266, Room 273, Washington, DC 20024. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record.

Arthur L. Neal,

Acting Director, USDA/1890 Programs.

[FR Doc. E8–19457 Filed 8–21–08; 8:45 am]

BILLING CODE 3410–01–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. AMS–ST–08–0069]

Plant Variety Protection Board; Open Teleconference Meeting

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of teleconference meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming teleconference meeting of the Plant Variety Protection Board. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend the meeting.

DATES: September 9, 2008; 1 p.m.–3 p.m. Eastern Daylight Time.

ADDRESSES: The meeting will be held in the United States Department of Agriculture, Agricultural Marketing Service Conference Room, Room 3074, South Building, 1400 Independence Avenue, SW., Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Janice M. Strachan, Plant Variety Protection Office (PVPO), Science and Technology Programs, Agricultural Marketing Service, United States Department of Agriculture, telephone number (301) 504–5518, fax (301) 504–5291, or e-mail *PVPOmail@usda.gov.*

SUPPLEMENTARY INFORMATION: The Plant Variety Protection (PVP) Board is authorized under section 7 of the Plant Variety Protection Act (7 U.S.C. 2327). The Board advises the Secretary of Agriculture on rules and regulations implementing the Act. On September 9, 2008, the Board will conduct a teleconference meeting to discuss improving the Plant Variety Protection Office Application Process and other related topics.

The tentative agenda for the teleconference meeting includes: (1) Welcome and opening remarks; (2) Action on general recommendations from Board minutes of May 1, 2008 teleconference meeting, (3) Financial status of the PVP Office, (4) PVP Office information technology infrastructure, (5) PVP outreach activities, and (6) Adjournment.

The public may attend the teleconference at the following address: USDA's Agricultural Marketing Service Conference Room, Room 3074, South Building, 1400 Independence Avenue, SW., Washington, DC 20250. All attendees are required to register with the PVP Office at 301–504–5518 before September 5, 2008. Identification will be required to be admitted to the USDA's South Building.

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation should be directed to the person listed under **FOR FURTHER INFORMATION CONTACT**. Minutes of the teleconference will be posted on the Internet Web site *http://www.ams.usda.gov/PVPO.*

Dated: August 18, 2008.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E8–19466 Filed 8–21–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2008–0030]

National Advisory Committee on Microbiological Criteria for Foods

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: This notice announces that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) will hold public meetings of the full Committee and Subcommittees on September 22–26, 2008. The Committee will discuss: (1) Parameters for inoculated-pack challenge study protocols, and (2) Determination of the most appropriate technologies for the Food Safety and Inspection Service (FSIS) to adopt in performing routine and baseline microbiological analyses.

DATES: The full Committee will hold an open meeting on Friday, September 26, 2008, from 9 a.m. to 1 p.m. The Subcommittee on parameters for inoculated-pack challenge study protocols will hold open meetings on Monday, September 22, and Tuesday, September 23, 2008, from 8:30 a.m. to 5 p.m. The Subcommittee on determination of the most appropriate technologies for the FSIS to adopt in performing routine and baseline microbiological analyses will hold open meetings on Wednesday, September 24, and Thursday, September 25, 2008, from 8:30 a.m. to 5 p.m.

ADDRESSES: The September 22–25, 2008, Subcommittee meetings will be held at the Aerospace Center, 901 D Street, SW., Rooms 369–371, Washington, DC 20024. The September 26, 2008, full Committee meeting will be held in the conference room at the south end of the U.S. Department of Agriculture (USDA) cafeteria located in the South Building, 1400 Independence Avenue, SW., Washington, DC 20250. All documents related to the full Committee meeting will be available for public inspection in the FSIS Docket Room, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 2534 South Building, Washington, DC 20250, between 8:30 a.m. and 4:30 p.m., Monday through Friday, as soon as they become available. The NACMCF documents will also be available on the Internet at *http://www.fsis.usda.gov/regulations/2008_Notices_Index/*.

FSIS will finalize an agenda on or before the meeting dates and post it on the FSIS Web page at *http://www.fsis.usda.gov/News/Meetings_&_Events/*.

Please note that the meeting agenda is subject to change due to the time required for Committee discussions; thus, sessions could start or end earlier or later than anticipated. Please plan accordingly if you would like to attend a particular session or participate in a public comment period.

Also, the official transcript of the September 26, 2008, full Committee meeting, when it becomes available, will be kept in the FSIS Docket Room at the above address and will also be posted on *http://www.fsis.usda.gov/About/NACMCF_Meetings/*.

The mailing address for the contact person is: Karen Thomas-Sharp, U.S. Department of Agriculture, FSIS, Office of Public Health Science, 1400 Independence Avenue, SW., 333 Aerospace Center, Washington, DC 20250–3766.

FOR FURTHER INFORMATION CONTACT: Persons interested in making a presentation, submitting technical papers, or providing comments at the September 26, plenary session should contact Karen Thomas-Sharp, phone (202) 690–6620, fax (202) 690–6334, e-mail *Karen.thomas-sharp@fsis.usda.gov*, or at the mailing address above. Persons requiring a sign language interpreter or other special accommodations should notify Mrs. Thomas-Sharp by September 17, 2008.

SUPPLEMENTARY INFORMATION:

Background

The NACMCF was established in 1988, in response to a recommendation of the National Academy of Sciences for an interagency approach to microbiological criteria for foods, and in response to a recommendation of the U.S. House of Representatives Committee on Appropriations, as expressed in the Rural Development, Agriculture, and Related Agencies Appropriation Bill for fiscal year 1988. The charter for the NACMCF is available for viewing on the FSIS Internet Web page at *http://www.fsis.usda.gov/About/NACMCF_Charter/*.

The NACMCF provides scientific advice and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services on public health issues relative to the safety and wholesomeness of the U.S. food supply, including development of microbiological criteria and review and evaluation of epidemiological and risk assessment data and methodologies for assessing microbiological hazards in foods. The Committee also provides scientific advice and recommendations to the Centers for Disease Control and Prevention and the Departments of Commerce and Defense.

Dr. H. Scott Hurd, Deputy Under Secretary for Food Safety, U.S. Department of Agriculture, is the Committee Chair; Dr. Stephen Sundlof, Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN), is the Vice-Chair; and Gerri Ransom, FSIS, is the Executive Secretary.

- At the subcommittee meetings the week of September 22–25, 2008 the groups will discuss:
- Parameters for inoculated-pack challenge study protocols, and
- Determination of the most appropriate technologies for the FSIS to adopt in performing routine and baseline microbiological analyses.

Documents Reviewed by NACMCF

FSIS intends to make available to the public all materials that are reviewed and considered by NACMCF regarding its deliberations. Generally, these materials will be made available as soon as possible after the full Committee meeting. Further, FSIS intends to make these materials available in electronic format on the FSIS Web page, as well as

in hard copy format in the FSIS Docket Room. Often, an attempt is made to make the materials available at the start of the full Committee meeting when sufficient time is allowed in advance to do so.

Disclaimer: NACMCF documents and comments posted on the FSIS Web site are electronic conversions from a variety of source formats. In some cases, document conversion may result in character translation or formatting errors. The original document is the official, legal copy.

In order to meet the electronic and information technology accessibility standards in Section 508 of the Rehabilitation Act, NACMCF may add alternate text descriptors for non-text elements (graphs, charts, tables, multimedia, etc.). These modifications only affect the online copies of the documents.

Copyrighted documents will not be posted on the FSIS Web site, but will be available for inspection in the FSIS Docket Room.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2008_Notices_Index/*. FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/*. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and they have the option to password protect their accounts.

Done at Washington, DC on August 19, 2008.

Alfred V. Almanza,

Administrator.

[FR Doc. E8–19540 Filed 8–21–08; 8:45 am]

BILLING CODE 3410–DM–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* September 21, 2008.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Kimberly M. Zeich, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@jwod.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On June 20 and June 27, 2008, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (73 FR35118; 35119; 36492) of proposed additions to the Procurement List.

The following comments pertain to Bulletin Rails; Bulletin Board; and Marker Board, Wall Mounted:

Comments were received from a contractor that provides some of the same commodities and is an authorized distributor of AbilityOne products. The contractor stated that adding the proposed products to the Procurement List will have a significantly adverse effect on her company. However, the contractor did not demonstrate that her firm holds a contract specifically for the proposed products versus holding a multiple award contract for a broad category of products such as office supplies. The Committee determined that its action will not have a severe adverse impact on this contractor, as the company continues to be able to do business with the government and may sell the AbilityOne products in lieu of commercial equivalents to its federal customers.

Comments were received from a manufacturer's representative group, stating that the addition of the proposed products to the Procurement List will have significant impact on her business and a substantial number of small entities who can no longer sell commercial equivalent products to federal customers. The commenter stated that companies are struggling to survive in the current economy without having to compete with AbilityOne. The commenter questioned whether the products would in fact be produced with 75% direct labor from people who are blind and whether the products would be compliant with the Trade Agreements Act (TAA).

The commenter did not support the claim that there was significant impact on her business with specific contract or financial information. As stated above, large and small office supply dealers will continue to be able to do business with the government if they become authorized to sell the AbilityOne manufactured products in the place of commercial equivalents. In addition, the AbilityOne Program pertains to federal purchasing, which is a small share of the U.S. market for office supplies. The nonprofit agency designated to manufacture the proposed products is in full compliance with Committee regulations for direct labor by people who are blind, and proposes to manufacture the subject items with 81% direct labor provided by people who are blind, creating over 10 new jobs annually for these individuals. The production will include several cutting functions, assembling, attaching/including hardware and packaging the products, constituting a substantial transformation. The resulting products, once added to the Procurement List, will be compliant with the TAA.

The following comment pertains to Stapler, Spring Power:

A comment was received from an AbilityOne nonprofit agency employing persons with severe disabilities that currently supplies staplers under the AbilityOne Program to Federal customers. In its comment, the nonprofit stated that the addition of the spring powered staplers would have a significant negative impact on its current line of staplers and indicated that the spring powered staplers should be awarded to them as a product line extension.

The Javits-Wagner-O'Day (JWOD) Act establishes a clear priority for products produced and offered for sale by qualified nonprofit agencies for the

blind over products produced and offered for sale by qualified nonprofit agencies for other severely handicapped (41 U.S.C. 47(d)(2)). National Industries for the Blind (NIB) has not previously waived the priority for all staplers in the stapler line. Spring powered staplers have been available to the Government from commercial vendors via GSA schedule contracts concurrent with the sale of the nonprofit's standard stapler for a considerable time; therefore the addition to the Procurement List of spring powered staplers will not have a severe adverse impact on the sale of standard staplers by the nonprofit agency.

The following material pertains to all of the items being added to the Procurement List:

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

Bulletin Rails

NSN: 7520–00–NIB–1801—48″, Natural Cork, Aluminum Frame.
NSN: 7520–00–NIB–1802—36″, Natural Cork, Aluminum Frame.
NSN: 7520–00–NIB–1803—24″, Natural Cork, Aluminum Frame.

Marker Board, Wall Mounted

NSN: 7110–00–NIB–0037—3′x2′ , Combo Dry Erase, Cork Board, Oak Finish.
NSN: 7110–00–NIB–0038—24″x18″, Melamine, Dry Erase Board, Thin Aluminum Frame.
NSN: 7110–00–NIB–0042—24″x18″, Cork Board, Oak Finish.
NSN: 7110–00–NIB–0047—3′x2′, Fabric Board, Grey, Black Plastic Radius Corners.
NSN: 7110–00–NIB–0048—4—12″x12″, Cork, Panels w/Adhesive Backing (no frame).
NSN: 7110–00–NIB–0050—1″x3″, Cork Board, Vertical, Slim Line Oak Finish.
NSN: 7110–00–NIB–0060—5′x3′, Porcelain Magnetic Dry Erase Board, Thick Aluminum.
NSN: 7110–01–416–5198—24″x18″, Melamine, Dry Erase Board, Thin Aluminum.
NSN: 7195–01–235–4161—3′x2′, Cork Board, Oak Finish.
Coverage: A-List for the total Government requirements as specified by the General Services Administration.

Bulletin Board

NSN: 7195–01–218–2026–4′x3′, Cork Board, Oak Finish.

Marker Board, Wall Mounted

NSN: 7110–00–NIB–0028—24″x13″, Dry Erase, Cubicle Board, Aluminum.
NSN: 7110–00–NIB–0029—30″x18″, Dry Erase, Cubicle Board, Aluminum.
NSN: 7110–00–NIB–0030—30″x18″, Combo Dry Erase, Cubicle Color Cork Board, Aluminum.
NSN: 7110–00–NIB–0031—30″x18″, Cubicle Color Cork Board, Aluminum.
NSN: 7110–00–NIB–0032—30″x18″, Dry Erase, 1 mo. Calendar, Aluminum.
NSN: 7110–00–NIB–0039—4′x3′, Combo Dry Erase, Cork Board, Oak Finish.
NSN: 7110–00–NIB–0040—6′x4′, Melamine Dry Erase Magnetic, Thick Aluminum Frame.
NSN: 7110–00–NIB–0043—6′x4′, Porcelain, Dry Erase Magnetic, Thick Aluminum Frame.
NSN: 7110–00–NIB–0045—24″x18″, In/Out Board System, Thin Aluminum Frame.
NSN: 7110–00–NIB–0046—4′x3′, Fabric Board, Black Plastic, Radius Corners.
NSN: 7110–00–NIB–0049—6′x4′, Cork Board, Thin Aluminum Frame.
NSN: 7110–00–NIB–0051—6′x4′, Cork Board, Oak Finish.
Coverage: B-List for the broad Government requirement as specified by the General Services Administration
NPA: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, WA.
Contracting Activity: General Service Administration, Federal Supply Service, National Furniture Acquisition Center, Arlington, VA.

Stapler, Spring Powered

NSN: 7520–00–NIB–1916—20 sheet capacity.
NSN: 7520–00–NIB–1917—60 sheet capacity.
NSN: 7520–00–NIB–1992—15 sheet capacity.
NSN: 7520–00–NIB–1993—25 sheet capacity.
Coverage: A-List for the total Government requirements as specified by the General Services Administration.
NPA: Winston-Salem Industries for the Blind, Winston-Salem, NC.
Contracting Activity: General Services Administration, Federal Supply Services, Region 2, New York, NY.

Services

Service Type/Location: Custodial Services, Illinois Military Academy, 1301 North MacArthur Road, Springfield, IL.
NPA: United Cerebral Palsy of the Land of Lincoln, Springfield, IL.
Contracting Activity: Illinois National Guard—Camp Lincoln, Springfield, IL.
Service Type/Location: Facilities Management, Naval Surface Warfare Center, Acoustic Research Detachment (ARD), Bayview, ID.
NPA: Skookum Educational Programs, Bremerton, WA.
Contracting Activity: Naval Facilities Engineering Command (NAVFAC), Silverdale, WA.

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Kimberly M. Zeich,

Director, Program Operations.

[FR Doc. E8–19476 Filed 8–21–08; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 080416579–81111–02]

Reopening of Request for Public Comments on Deemed Export Advisory Committee Recommendations: Narrowing the Scope of Technologies on the Commerce Control List Subject to Deemed Export Licensing Requirements and Implementing a More Comprehensive Set of Criteria for Assessing Probable Country Affiliation for Foreign Nationals

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry; reopening of comment period.

SUMMARY: This notice reopens the comment period on the notice of inquiry (73 FR 28795) that sought comments regarding two specific recommendations made by the Deemed Export Advisory Committee (DEAC) with respect to the Bureau of Industry and Security's (BIS's) deemed export licensing policy. The new comment period deadline is September 22, 2008.

DATES: Comments must be received no later than September 22, 2008.

FOR FURTHER INFORMATION CONTACT: Steven Emme, Regulatory Policy Division, 202–482–2440,

semme@bis.doc.gov. The DEAC report may be accessed at *http://tac.bis.doc.gov/2007/deacreport.pdf.*

ADDRESSES: You may submit comments, identified by ''DEAC Report comments,'' by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *rpd2@bis.doc.gov.* Include ''DEAC Report comments'' in the subject line of the message.
- Fax: 202–482–3355
- Hand Delivery/Courier: Steven Emme, U.S. Department of Commerce, Bureau of Industry and Security, Regulatory Policy Division, 14th & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230, ATTN: DEAC Report comments.

SUPPLEMENTARY INFORMATION: On May 19, 2008, the Bureau of Industry and Security (BIS) published a notice of inquiry (73 FR 28795) to elicit comments regarding two specific recommendations made by the Deemed Export Advisory Committee (DEAC) with respect to the Bureau of Industry and Security's (BIS's) deemed export licensing policy. BIS is continuing to seek comments on whether the scope of technologies on the Commerce Control List that are subject to deemed export licensing requirements should be narrowed, and if so, which technologies should be subject to deemed export licensing requirements. Additionally, BIS is continuing to seek comments on whether a more comprehensive set of criteria should be used to assess country affiliation for foreign nationals with respect to deemed exports.

The original deadline for comments was August 18, 2008. BIS is now reopening the comment period to allow the public more time to comment on this notice of inquiry. The new comment period will end September 22, 2008.

Dated: August 18, 2008.

Bernard Kritzer,

Director, Office of Exporter Services.

[FR Doc. E8–19558 Filed 8–21–08; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

(A–533–847, A–570–934)

1–Hydroxyethylidene–1, 1–Diphosphonic Acid from the Republic of India and the People's Republic of China: Postponement of Preliminary Determinations of Antidumping Duty Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 22, 2008.

FOR FURTHER INFORMATION CONTACT: Brian C. Smith (India) or Maisha Cryor (People's Republic of China), AD/CVD Operations, Offices 2 and 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–5831, respectively.

SUPPLEMENTARY INFORMATION:

Postponement of Preliminary Determinations

On April 8, 2008, the Department of Commerce (the Department) initiated the antidumping investigations on 1–Hydroxyethylidene–1, 1–Diphosphonic Acid from the Republic of India and the People's Republic of China. *See 1–Hydroxyethylidene–1, 1–Diphosphonic Acid from the Republic of India and the People's Republic of China: Initiation of Antidumping Duty Investigations*, 73 FR 20023 (April 14, 2008). The notice of initiation stated that the Department would issue the preliminary determinations for these investigations no later than 140 days after the date of issuance of the initiation, in accordance with section 773(b)(1)(A) of the Tariff Act of 1930, as amended (the Act).

On July 30, 2008, the petitioner, Compass Chemical International LLC, made a request pursuant to 19 CFR 351.205(b)(2) and (e) for a 50–day postponement of the preliminary determinations. The petitioner requested postponement of the preliminary determinations in order to allow more time to analyze and comment on the respondents' questionnaire responses.

For the reasons identified by the petitioner and because there are no compelling reasons to deny the request, the Department is postponing the deadline for the preliminary determinations under section 773(c)(1)(A) of the Act by 50 days from the current deadline of August 26, 2008, to October 15, 2008. The deadline for the final determinations will continue to be 75 days after the date of the preliminary determinations, unless extended.

This notice is issued and published pursuant to sections 733(c)(2) of the Act and 19 CFR 351.205 (f)(1).

Dated: August 14, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–19555 Filed 8–21–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Institute of Standards and Technology Performance Review Board Membership

The National Institute of Standards and Technology Performance Review Board (NIST PRB) reviews performance appraisals, agreements, and recommended actions pertaining to employees in the Senior Executive Service and reviews performance-related pay increases for ST–3104 employees. The Board makes recommendations to the appropriate appointing authority concerning such matters so as to ensure the fair and equitable treatment of these individuals.

This notice lists the membership of the NIST PRB and supersedes the list published in **Federal Register** Vol. 72, No. 179, pages 52859–52860, on September 17, 2007.

Eric Amis (C) (alternate), Deputy Director, Materials Science and Engineering Laboratory, National Institute of Standards & Technology, Gaithersburg, MD 20899, Appointment Expires: 12/31/10.

W. Todd Grams (C) (alternate), Chief Financial Officer, National Institute of Standards & Technology, Gaithersburg, MD 20899, Appointment Expires: 12/31/10.

Stella Fiotes (C), Chief Facilities Management Officer, National Institute of Standards & Technology, Gaithersburg, MD 20899, Appointment Expires: 12/31/10.

James Olthoff (C), Deputy Director, Electronics and Electrical Engineering Laboratory, National Institute of Standards & Technology, Gaithersburg, MD 20899, Appointment Expires: 12/31/10.

Patricia Sefcik (C), Senior Director to the Deputy Assistant Secretary for Manufacturing, Manufacturing and Services, International Trade Administration, Washington, DC

20230, Appointment Expires: 12/31/10.

Sivaraj Shyam-Sunder (C) (alternate), Director, Building and Fire Research Laboratory, National Institute of Standards & Technology, Gaithersburg, MD 20899, Appointment Expires: 12/31/10.

Dated: August 19, 2008.

James M. Turner,

Deputy Director, National Institute of Standards and Technology Department of Commerce.

[FR Doc. E8–19556 Filed 8–21–08; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XI26

Availability of a Draft Environmental Impact Statement and Habitat Conservation Plan, and Receipt of Applications for Incidental Take Permits

AGENCY: Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce

ACTION: Notice of availability, receipt of applications.

SUMMARY: This notice advises the public that the Oregon Department of Forestry (ODF), has submitted applications to the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) for incidental take permits (Permit(s)) pursuant to the Endangered Species Act of 1973, as amended (ESA). As required by the ESA, ODF has also prepared a Habitat Conservation Plan (Plan) designed to minimize and mitigate any such take of endangered or threatened species. The Permit applications are related to forest management and timber harvest activities on the Elliott State Forest in Coos and Douglas Counties, Oregon. The FWS and NMFS (together, the Services) are co-lead agencies in this effort.

The Permit applications include the proposed Plan and a draft Implementation Agreement (IA). The Services also announce the availability of a draft Environmental Impact Statement (DEIS) for the proposed action.

The Services are requesting comments from the public on the Permit applications, the Plan, the IA, and DEIS, all of which are available for review. The Services are furnishing this notice to allow other agencies and the public an opportunity to review and comment on these documents. All comments received will become part of the public record and will be available for review pursuant to the ESA. For locations to review the documents, please see the SUPPLEMENTARY INFORMATION section below. A 90–day comment period, rather then a standard 60–day comment period, is being provided to allow the public sufficient time to comment on the draft documents.

DATES: All comments must be received no later than November 20, 2008.

ADDRESSES: All written comments should be addressed to: Lee Folliard, U.S. Fish and Wildlife Service, 2600 SE 98th Avenue, Suite 100, Portland, OR 97266, facsimile: (503) 231–6195; or Chuck Wheeler, National Marine Fisheries Service, 2900 NW Stewart Parkway, Roseburg, OR 97470–1274, facsimile: (541) 957–3386. Comments may also be submitted by e-mail to *ElliottHCP@fws.gov* or *ElliottStateForest.nwr@noaa.gov*. In the subject line of the email include the identifier Elliott State Forest HCP EIS.

FOR FURTHER INFORMATION CONTACT: For further information or to receive copies of the documents on CD ROM, please contact Lee Folliard at (503) 231–6179; or Chuck Wheeler, (541) 957–3379.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Copies of the draft documents are available for public inspection and review, by appointment, at the above addresses during normal business hours or by requesting copies on CD ROM by contacting the Services (see FOR FURTHER INFORMATION section above). The documents are also available on the Internet at *http://www.fws.gov/oregonfwo/ToolsForLandowners/HabitatConservationPlans/* or at the following offices or libraries:

Oregon Department of Forestry, 2600 State Street, Building C, Salem, OR 97310

Oregon Department of Forestry, 63612 Fifth Road, Coos Bay, OR 97420

Oregon State Library, 250 Winter Street NE, Salem, OR 97301–3950

Coos Bay Public Library, 525 Anderson Avenue, Coos Bay, OR 97420

North Bend Public Library, 1800 Sherman Avenue, North Bend, OR 97459

Douglas County Library, 1409 NE Diamond Lake Boulevard, Roseburg, OR 97470.

Background

Section 9 of the ESA and Federal regulations prohibits the taking of a species listed as endangered or threatened. The term take is defined under the ESA to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Harm is defined to include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, and sheltering.

Section 10(a) of the ESA and its implementing regulations specify the requirements for issuance of permits to non-Federal parties for the take of listed species. Any proposed take must be incidental to, and not the purpose of, otherwise lawful activities, must not appreciably reduce the likelihood of the survival and recovery of the species in the wild, and must minimize and mitigate the impact of such take to the maximum extent practicable. FWS regulations governing permits for threatened and endangered species are promulgated in 50 CFR 13.21. NMFS regulations governing permits for threatened and endangered species are promulgated at 50 CFR 222.307.

The Elliott State Forest encompasses approximately 93,000 acres of state-owned forestlands in Coos and Douglas Counties in Oregon's Coast Range. ODF manages the Elliott State Forest out of its Coos District Office, located in Coos Bay. The action area for this proposal focuses on a mostly contiguous block of land approximately 18 miles long from north to south, and about 16 miles wide from west to east. An additional 4,000 acres, scattered tracts in Coos, Douglas, and Curry Counties, were originally included as part of the action area, but have been removed from the proposal by the applicant.

The Elliott State Forest is managed in accordance with the 1994 Elliott State Forest Management Plan (FMP). ODF currently holds a section 10(a)(1)(B) Permit for potential incidental take of the northern spotted owl on the Elliott State Forest; the Permit and associated Plan went into effect in 1995. ODF is proposing to manage the forest according to a revised FMP that would go into effect concurrently with the proposed Plan. Some of the proposed forest management activities have the potential to affect the northern spotted owl, as well as other species subject to protection under the ESA, including the

marbled murrelet (Brachyramphus marmoratus) and Oregon Coast coho salmon (*Oncorhynchus kisutch*). As a result, ODF prepared a new, 50–year Plan, based on the revised FMP that would address incidental take of all these listed species, as well as 15 unlisted species (covered species). This new Plan forms the basis of ODF's current Permit applications, and is the proposed action in the Services' DEIS.

The Permit application ODF submitted to the FWS addresses the potential take of northern spotted owl and marbled murrelet, which are listed as threatened under the ESA. Unlisted species under FWS's jurisdiction included in ODF's application, and which would receive incidental take allowance should they be listed during the term of the Plan, are the bald eagle (*Haliaeetus leucocephalus*), northern goshawk (*Accipiter gentilis*), olive-sided flycatcher (*Contopus borealis*), western bluebird (*Sialia mexicana*), coastal cutthroat trout (*Oncorhynchus clarki clarki*), Pacific lamprey (*Lampetra tridentatus*), river lamprey (*Lampetra ayresi*), brook lamprey (*Lampetra richardsoni*), fisher (*Martes pennanti*), southern torrent salamander (*Rhyacotriton variegates*), red-legged frog (*Rana aurora*), and coastal tailed frog (*Ascaphus truei*). The fisher is currently a candidate for listing under the ESA.

The Permit application ODF submitted to the NMFS addresses the potential take of Oregon Coast coho salmon (*Oncorhynchus kisutch*), which is listed as threatened under the ESA. Unlisted species under NMFS's jurisdiction included in ODF's application, and which would receive incidental take allowance should they be listed during the term of the Plan, are Chinook salmon (*Oncorhynchus tshawytscha*), chum salmon (*Oncorhynchus keta*), and steelhead trout (*Oncorhynchus mykiss*).

Activities that ODF is proposing for Permit coverage include:

1. Mechanized timber harvest;
2. Forest product transportation;
3. Road and landing construction, use, maintenance, and abandonment;
4. Site preparation and tree planting (excluding use of herbicides);
5. Site Fertilization;
6. Silvicultural practices;
7. Fire suppression;
8. Aquatic habitat restoration;
9. Rock pit development; and
10. Other management activities, including vertebrate control and harvesting of minor forest products, and
11. Research and monitoring.

The Services formally initiated an environmental review of the project through publication of a Notice of Intent to prepare an Environmental Impact Statement in the **Federal Register** on May 9, 2005 (70 FR 24450). That notice also announced a public scoping period during which interested parties were invited to provide written comments expressing their issues or concerns relating to the proposal, and to attend public scoping meetings held in Roseburg, North Bend, and Salem, Oregon.

Based on public scoping comments, the Services prepared a DEIS to analyze the effects of alternatives on the human environment. Alternative 2 in the DEIS is described as implementation of ODF's Plan, FWS issuance of a Permit for northern spotted owl, marbled murrelet, and other unlisted species, and NMFS issuance of a Permit for Oregon Coast coho salmon, and other unlisted species, should they become listed during the term of the Plan. Two other alternatives are analyzed in the DEIS: Alternative 1, No-Action, under which ODF would continue operating under the existing FMP and incidental take permit for northern spotted owls only; and, Alternative 3, Increased Stream Buffers and Intensive Forestry, under which ODF would manage approximately one-half of the action area on a short rotation (40–50 years), and the remainder of the lands would be designated conservation areas around core areas and riparian buffer areas.

Note that at the time the Notice of Intent was published for this project (70 FR 24450), Oregon Coast coho salmon was proposed for ESA listing as a threatened species. The Notice of Intent indicated that ODF was expected to submit a Permit application to NMFS for incidental take of Oregon Coast coho salmon, and three unlisted fish species under NMFS' jurisdiction, should they become listed in the future. NMFS has since determined that the Oregon Coast coho salmon does warrant listing as a threatened species (73 FR 7816).

This notice is provided pursuant to ESA and the National Environmental Policy Act of 1969, as amended. The Services will evaluate the applications, associated documents, and comments submitted thereon to determine whether the applications meet the requirements of the ESA and National Environmental Policy Act. The Services are particularly interested in comments pertaining to the application requirements under 50 CFR 17.22(b)(1). These include whether the Plan: provides complete descriptions of the activities under which the incidental taking of covered species is likely to occur; describes the impacts to covered species individuals that will likely result from the incidental taking; outlines the steps ODF will take to monitor, minimize, and mitigate such impacts for each covered species and the available funding to implement such steps over the term of the Permits; and, describes alternative actions to such taking and the reasons why such alternatives are not proposed to be utilized. As part of evaluating whether the permit issuance criteria are met, the Services specifically seek comment on whether the minimization and mitigation measures are being undertaken to the maximum extent practicable. In addition, the FWS is seeking comment on the assumptions regarding how suitable habitat is being defined for all the covered species, as well as assumptions about the development of those species habitat over time.

The Services will revise the DEIS in a Final Environmental Impact Statement (FEIS). The Services decision of whether to issue Permits will be made upon completion of the FEIS and the associated Record of Decision.

Dated: June 26, 2008.

David Patte,

Acting Regional Director, Fish and Wildlife Service, Region 1, Portland, Oregon.

Dated: August 13, 2008.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E8–19575 Filed 8–21–08; 8:45 am]

BILLING CODES 4310–55–S, 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XJ77

Marine Mammals; File No. 774–1847–03

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

ACTION: Notice; issuance of permit amendment.

SUMMARY: Notice is hereby given that NMFS Southwest Fisheries Science Center, Antarctic Marine Living Resources Program (Rennie Holt, Ph.D., Principal Investigator), 8604 La Jolla Shores Drive, La Jolla, CA 92037 has been issued an amendment to Scientific Research Permit No. 774–1847–02.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018.

FOR FURTHER INFORMATION CONTACT: Kate Swails or Tammy Adams, (301)713–2289.

SUPPLEMENTARY INFORMATION: On June 2, 2008 notice was published in the **Federal Register** (73 FR 31436) that an amendment of Permit No. 774–1847–02 had been requested by the above-named organization. The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Permit No. 774–1847–02, issued October 11, 2007 (72 FR 57914), authorizes the permit holder to continue a long-term ecosystem monitoring program of pinniped species in the South Shetland Islands, Antarctica. The permit holder is authorized to take up to 710 Antarctic fur seals (Arctophalus gazell) and 20 leopard seals (Hydrurga leptonyx) annually. The animals are captured, measured, weighed, tagged, blood sampled, and have time-depth recorders, VHF transmitters, and platform terminal transmitters attached. A subset of fur seals are given an enema, have a tooth extracted, milk sampled, and are part of a doubly-labeled water study on energetics. A subset of leopard seals are blubber and muscle sampled. Annual research-related mortality of up to eight Antarctic fur seals (3 adults and 5 pups) and two leopard seals is also authorized.

The amendment authorizes the permit holder to collect tissue samples from and bleach mark 50 leopard seals. Additional capture is not required to collect these samples. The amendment also authorizes the researchers to begin a southern elephant seal (Mirounga leonina) study. Up to 180 southern elephant seals would be captured, measured, and tagged annually. A subset would have blood and vibrissae collected, muscle/blubber biopsied, and satellite tags attached. The permit amendment authorizes up to four research-related mortalities (two adults and two juveniles) of southern elephant seals. The amendment is valid until September 30, 2011.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: August 14, 2008.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E8–19577 Filed 8–21–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XJ68

Incidental Takes of Marine Mammals Incidental to Specified Activities; Harbor Activities Related to the Delta IV/Evolved Expendable Launch Vehicle at Vandenberg Air Force Base, CA

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

ACTION: Notice; issuance of incidental harassment authorization.

SUMMARY: In accordance with the provisions of the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to United Launch Alliance (ULA) to take small numbers of marine mammals, by Level B harassment only, incidental to harbor activities related to the Delta IV/Evolved Expendable Launch Vehicle (EELV) at south Vandenberg Air Force Base, CA (VAFB).

DATES: This authorization is effective from August 20, 2008 through August 19, 2009.

ADDRESSES: A copy of the IHA and the application are available by writing to P. Michael Payne, Chief, Permits, Conservation, and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225, or by telephoning the contact listed here. A copy of the application may be obtained by writing to this address, by telephoning the contact listed here (**FOR FURTHER INFORMATION CONTACT**) or online at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*. Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Jeannine Cody or Candace Nachman, (301) 713–2289.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by United States citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings may be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for certain subsistence uses, and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such taking are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as:

> ''...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except for certain categories of activities not pertinent here, the MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [(Level A harassment(]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [(Level B harassment(].

Section 101(a)(5)(D) establishes a 45–day time limit for NMFS' review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Summary of Request

On February 18, 2008, NMFS received an application from ULA requesting an

authorization for the harassment of small numbers of Pacific harbor seals (**PHOCA VITULINA RICHARDSI**) and California sea lions (*Zalophus californianus*) incidental to harbor activities related to the Delta IV/EELV, including: transport vessel operations, cargo movement activities, harbor maintenance dredging, and kelp habitat mitigation operations. In addition, northern elephant seals (*Mirounga angustirostris*) may also be incidentally harassed but in even smaller numbers. IHAs were issued to The Boeing Company, now ULA, on May 15, 2002 (67 FR 36151, May 23, 2002), May 20, 2003 (68 FR 36540, June 18, 2003), May 20, 2004 (69 FR 29696, May 25, 2004), May 23, 2005 (70 FR 30697, May 27, 2005), June 20, 2006 (71 FR 36321, June 26, 2006), and June 21, 2007 (72 FR 34444, June 22, 2007) each for a 1–year period. No work and, therefore, no monitoring was conducted under the 2007 IHA. The harbor where activities will take place is on south VAFB approximately 2.5 miles (mi) (4.02 kilometers (km)) south of Point Arguello, CA and approximately 1 mi (1.61 km) north of the nearest marine mammal pupping site (i.e., Rocky Point).

Additional background relating to this application and the scope of the activities is set forth in the proposed IHA notice (73 FR 38176, July 3, 2008) and is not repeated here. The activities to be conducted have not changed between the proposed IHA notice and this final notice announcing the issuance of the IHA.

Specified Activities

The *Delta Mariner* is a 312 foot (ft)-long (95.1–meter (m)), 84 ft-wide (25.6 m) steel hull ocean-going vessel capable of operating at an 8 ft (2.4–m) draft. Containers containing flight hardware items will be towed off the *Delta Mariner* by a tractor tug that generates a sound level of approximately 87 decibels (dB) A-weighted at 50 ft (15.2 m) while in operational mode. Total docking and cargo movement activities is estimated to be approximately 14 to 18 hours (hr) in good weather.

To accommodate the *Delta Mariner*, the harbor will need to be dredged, removing up to 5,000 cubic yards of sediment per dredging. Dredging will involve the use of heavy equipment, including a clamshell dredge, dredging crane, a small tug, dredging barge, dump trucks, and a skip loader. Measured sound levels from this equipment are roughly equivalent to those estimated for the wharf modification equipment: 43 to 81 dB A-weighted at 250 ft (76.2 m). Dredge operations, from set-up to tear-down, would continue 24–hr a day for 3 to 5 weeks. Sedimentation surveys have shown that initial dredging indicates that maintenance dredging should be required annually or twice per year, depending on the hardware delivery schedule.

A more detailed description of the work proposed for 2008 is contained in the application which is available upon request (see **ADDRESSES**) and in the Final U.S. Air Force Environmental Assessment for Harbor Activities Associated with the Delta IV Program at Vandenberg Air Force Base (ENSR International, 2001).

Comments and Responses

On July 3, 2008 (73 FR 38176), NMFS published a notice of receipt of proposed IHA for ULA(s request to take marine mammals, by harassment, incidental to harbor activities related to the Delta IV/EELV, including: transport vessel operations, cargo movement activities, harbor maintenance dredging, and kelp habitat mitigation and requested comments, information, and suggestions concerning the request. During the 30–day public comment period, NMFS received one comment from the Marine Mammal Commission (Commission), which recommended that NMFS issue the authorization as proposed.

Comment: The Commission recommends that NMFS approve the request provided that all reasonable measures will be taken to ensure the least practicable impact on the subject species and the required mitigation and monitoring activities are carried out as described in the July 3, 2008 **Federal Register** notice and the IHA application.

Response: NMFS agrees with the Commission's recommendation, and all monitoring and mitigation measures described in the previous **Federal Register** notices (67 FR 36151, May 23, 2002; 68 FR 36540, June 18, 2003; 69 FR 29696, May 25, 2004; 70 FR 30697, May 27, 2005; 71 FR 36321, June 26, 2006; and 72 FR 34444, June 22, 2007) are required in the current IHA.

Marine Mammals Affected by the Activity

The marine mammal species likely to be harassed incidental to harbor activities at south VAFB are the Pacific harbor seal, California sea lion, and northern elephant seal, which haul out in the area where these activities are conducted. None of the haul-out areas near these activities are used for breeding, molting, or mating. A more detailed discussion of the status of these stocks and their occurrence at VAFB, as well as other marine mammal species that occur at VAFB, was included in the notice of the proposed IHA (73 FR 38176, July 3, 2008).

Potential Effects of Activities on Marine Mammals

The primary impacts to marine mammals from these activities are expected to be short-term behavioral reactions in response to the acoustic and visual stimuli produced by the heavy machinery used. NMFS anticipates that no injury will result from these actions. A discussion of the sound levels produced by the equipment, behavioral reactions of marine mammals to loud noises or looming visual stimuli, and some specific observations of the response of marine mammals to this activity gathered during previous monitoring were presented in the notice of proposed IHA (73 FR 38176, July 3, 2008) and is not repeated here. For a further discussion of anticipated effects of the planned activities on pinnipeds in the area, refer to the application, NMFS(2005 Environmental Assessment (EA) and ENSR International(s 2001 Final EA.

Numbers of Marine Mammals Expected to be Harassed

ULA estimates that a maximum of 43 harbor seals per day may be hauled out near the south VAFB harbor, with a daily average of 21 seals sighted when tidal conditions were favorable during previous harbor dredging operations. Considering the maximum and average number of seals hauled out per day, assuming that the seals may be seen twice a day, and using a maximum total of 73 operating days in 2008–2009, NMFS estimates that a maximum of 767 to 1,570 Pacific harbor seals may be subject to Level B harassment out of a total estimated population of 31,600. These numbers are small relative to this population size (2.4 - 5 percent).

During wharf modification activities, a maximum of six California sea lions were seen hauling out in a single day. Based on the above-mentioned calculation, NMFS believes that a maximum of 219 California sea lions may be subject to Level B harassment out of a total estimated population of 240,000. These numbers are small relative to this population size (less than 0.1 percent). Up to 10 northern elephant seals (because they may be in nearby waters) may be subject to Level B harassment out of a total estimated population of 101,000. These numbers are small relative to this population size (less than 0.01 percent).

Possible Effects of Activities on Marine Mammal Habitat

ULA does not anticipate any loss or modification to the habitat used by Pacific harbor seals or California sea lions that haul out near the south VAFB harbor. The harbor seal and sea lion haul-out sites near south VAFB harbor are not used as breeding, molting, or mating sites; therefore, it is not expected that the activities in the harbor will have any impact on the ability of Pacific harbor seals or California sea lions in the area to reproduce.

ULA anticipates unavoidable kelp removal during dredging. This habitat modification will not affect the marine mammal habitat. However, ULA will mitigate for the removal of kelp habitat by placing 150 tons of rocky substrate in a sandy area between the breakwater and the mooring dolphins to enhance an existing artificial reef. This type of mitigation was implemented by the U.S. Army Corps of Engineers following the 1984 and 1989 dredging.

The anticipated negative effects of dredging and kelp mitigation (short-term increase in noise and sedimentation) will be short-term and are not expected to result in a loss or modification to the habitat used by Pacific harbor seals, California sea lions, or northern elephant seals that haul out near the south VAFB harbor. Additional details were provided in the notice of proposed IHA (73 FR 38176, July 3, 2008).

Mitigation

To reduce the potential for disturbance from visual and acoustic stimuli associated with the activities, ULA and/or its designees will undertake the following marine mammal mitigating measures:

(1) If activities occur during nighttime hours, lighting will be turned on before dusk and left on the entire night to avoid startling pinnipeds at night.

(2) Activities will be initiated before dusk.

(3) Construction noises will be kept constant (i.e., not interrupted by periods of quiet in excess of 30 minutes) while pinnipeds are present.

(4) If activities cease for longer than 30 minutes and pinnipeds are in the area, start-up of activities will include a gradual increase in noise levels.

(5) A NMFS-approved marine mammal observer will visually monitor the pinnipeds on the beach adjacent to the harbor and on rocks for any flushing or other behaviors as a result of ULA's activities (see Monitoring).

(6) To the extent possible, the *Delta Mariner* and accompanying vessels will enter the harbor only when the tide is too high for harbor seals to haul-out on the rocks. The vessel will reduce speed 1.5 to 2 knots (2.8–3.7 km/hr) once the vessel is within 3 mi (4.83 km) of the harbor. The vessel will enter the harbor stern first, approaching the wharf and mooring dolphins at less than 0.75 knot (1.4 km/hr).

(7) As alternate dredge methods are explored, the dredge contractor may introduce quieter techniques and equipment.

Monitoring

As part of its 2002 application, Boeing, now ULA, provided a proposed monitoring plan for assessing impacts to harbor seals from the activities at south VAFB harbor and for determining when mitigation measures should be employed. NMFS is requiring the same plan for this IHA.

A NMFS-approved and VAFB-designated biologically trained observer will monitor the area for pinnipeds during all harbor activities. During nighttime activities, the harbor area will be illuminated, and the monitor will use a night vision scope. Monitoring activities will consist of:

(1) Conducting baseline observation of pinnipeds in the project area prior to initiating project activities.

(2) Conducting and recording observations on pinnipeds in the vicinity of the harbor for the duration of the activity occurring when tides are low enough for pinnipeds to haul out

(2) ft, 0.61 m, or less).

(3) Conducting post-construction observations of pinniped haul-outs in the project area to determine whether animals disturbed by the project activities return to the haul-out.

Monitoring results from previous years of these activities have been reviewed and incorporated into the analysis of potential effects in this document, as well as the take estimates.

Reporting

ULA will notify NMFS two weeks prior to initiation of each activity. ULA will submit a draft report on all activities, 120 days prior to the expiration of this Authorization if a new Authorization will be requested for 2009–2010, and a final report within 120 days after the expiration of this Authorization, regardless of whether or not a new Authorization will be requested. The report will provide dates, times, durations and locations of specific activities, details of pinniped behavioral observations, and estimates of numbers of affected pinnipeds and impacts (behavioral or other). In addition, the report will include information on the weather, tidal state, horizontal visibility, and composition (species, gender, and age class) and locations of haul-out group(s). In the unanticipated event that any cases of pinniped injury or mortality are judged to result from these activities, ULA or its designee shall cease operations immediately and report the incident to NMFS immediately.

Endangered Species Act (ESA)

This action will not affect species listed under the ESA that are under the jurisdiction of NMFS. VAFB formally consulted with U.S. Fish and Wildlife Service in 1998 on the possible take of southern sea otters during Boeing(s, now ULA, harbor activities at south VAFB. A Biological Opinion was issued in August 2001, which concluded that the EELV Program is not likely to jeopardize the continued existence of the southern sea otter and no injury or mortality is expected. The activities covered by this IHA are analyzed in that Biological Opinion, and this IHA does not modify the action in a manner that was not previously analyzed.

National Environmental Policy Act

In 2001, the United States Air Force (USAF) prepared an EA for harbor activities associated with the Delta IV Program at VAFB. In 2005, NMFS prepared an EA supplementing the information contained in the USAF EA and issued a Finding of No Significant Impact (FONSI) on the issuance of an IHA for Boeing(s, now ULA, harbor activities in accordance with section 6.01 of the National Oceanic and Atmospheric Administration Administrative Order 216–6 (Environmental Review Procedures for Implementing the National Environmental Policy Act, May 20, 1999). ULA's activities and impacts for 2008–2009 are expected to be within the scope of NMFS(2005 EA and FONSI.

Determinations

NMFS has determined that the impact of harbor activities related to the Delta IV/EELV at VAFB (transport vessel operations, cargo movement activities, harbor maintenance dredging, and kelp habitat mitigation) will result in the Level B Harassment of small numbers of Pacific harbor seals, California sea lions, and northern elephant seals. The effects of ULA(s harbor activities are expected to be in the form of short-term and localized behavioral changes, and no take by injury or death is anticipated or authorized. NMFS has further determined that these takes will have a negligible impact on the affected marine mammal species and stocks.

While the number of incidental harassment takes will depend on the distribution and abundance of marine mammals in the vicinity of the activity, the number of potential harassment takings is estimated to be small (less than five percent of any of the estimated population sizes) and has been mitigated to the lowest level practicable through incorporation of the measures mentioned previously in this document.

The provision requiring that the activity not have an unmitigable adverse impact on the availability of the affected species or stock for subsistence uses is not implicated by this action.

Northern fur seals, Guadalupe fur seals, and Steller sea lions are unlikely to be found in the area and, therefore, will not be affected. No rookeries, mating grounds, areas of concentrated feeding, or other areas of special significance for marine mammals occur within or near south VAFB harbor.

Authorization

As a result of these determinations, NMFS has issued an IHA to ULA to take marine mammals, by Level B harassment, incidental to conducting harbor activities at VAFB for a one-year period, provided that the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: August 18, 2008.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E8–19582 Filed 8–21–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Office of the Secretary

Advisory Council on Dependents' Education

AGENCY: Department of Defense Education Activity (DoDEA), DoD.

ACTION: Notice of open meeting.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, the Department of Defense announces the following Federal advisory committee meeting of the Advisory Council on Dependents' Education.

DATES: Tuesday, September 23, 2008 (8 a.m. to 5 p.m., Eastern Daylight Time).

ADDRESSES: DoDEA Headquarters, Webb Building, 9th Floor, Director's Conference Room, 4040 North Fairfax Drive, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Jarrard, at (703) 588–3121, or at *james.jarrard@hq.dodea.edu.*

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: Recommend to the Director, DoDEA, general policies for the operation of the Department of Defense Dependents Schools (DoDDS); provide the Director with information about effective educational programs and practices that should be considered by DoDDS; and perform other tasks as may be required by the Secretary of Defense.

Agenda: The meeting agenda will be the current operational qualities of schools and the institutionalized school improvement processes, as well as other educational matters.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis. Appropriate government issued identification will be required to enter the meeting facility, which is a controlled access facility.

Committee's Point of Contact: Mr. Jim Jarrard, tel. (703) 588–3121, 4040 North Fairfax Drive, Arlington, VA 22203, e-mail: *james.jarrard@hq.dodea.edu.*

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the Advisory Council on Dependents' Education about its mission and functions. Written statements may be submitted at any time or in response to the stated agenda of the planned meeting of the Advisory Council on Dependents' Education.

All written statements shall be submitted to the Designated Federal Officer for the Advisory Council on Dependents' Education and this individual will ensure that the written statements are provided to the membership for their consideration. For the next meeting of the Advisory Council on Dependents' Education, Mr. Jim Jarrard, telephone (703) 588–3121, 4040 North Fairfax Drive, Arlington, VA 22203; e-mail: *james.jarrard@hq.dodea.edu*, will be acting in the capacity of the Designated Federal Officer for this committee.

Statements being submitted in response to the agenda mentioned in this notice must be received by the Designated Federal Officer at the address listed above at least fourteen calendar days prior to the meeting which is the subject of this notice. Written statements received after this date may not be provided to or considered by the Advisory Council on Dependents' Education until its next meeting.

The Designated Federal Officer will review all timely submissions with the Advisory Council on Dependents' Education Chairpersons and ensure they are provided to all members of the Advisory Council on Dependents' Education before the meeting that is the subject of this notice.

Oral Statements by the Public to the Membership: Pursuant to 41 CFR 102–3.140(d), time will be allotted for public comments to the Advisory Council on Dependents' Education. Individual comments will be limited to a maximum of five minutes' duration. The total time allotted for public comments will not exceed thirty minutes.

Dated: August 12, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–19499 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Closed Meeting of the Defense Policy Board Advisory Committee

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: The Defense Policy Board Advisory Committee will meet in closed session on September 25, 2008 from 0800 until 1830 and September 26, 2008 from 0800 until 1200 at the Pentagon.

The purpose of the meeting is to provide the Secretary of Defense, Deputy Secretary of Defense and Under Secretary of Defense for Policy with independent, informed advice on major matters of defense policy. The Board will hold classified discussions on national security matters.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law No. 92–463, as amended [5 U.S.C. App II (1982)], it has been determined that this meeting concerns matters listed in 5 U.S.C. 552B (c)(1)(1982), and that accordingly this meeting will be closed to the public.

Dated: August 15, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–19496 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Strategic Environmental Research and Development Program, Scientific Advisory Board

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: This Notice is published in accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463). The topic of the meeting on September 9–11, 2008 are to review new start and continuing research and development projects requesting Strategic Environmental Research and Development Program funds in excess of $1M. This meeting is open to the public. Any interested person may attend, appear before, or file statements with the Scientific Advisory Board at the time and in the manner permitted by the Board.

DATES: Tuesday, September 9, 2008, from 9 a.m. to 5 p.m.; Wednesday, September 10, 2008, from 9 a.m. to 5 p.m.; and Thursday, September 11, 2008, from 8:30 a.m. to 4 p.m.

ADDRESSES: SERDP Office Conference Center, 901 North Stuart Street, Suite 804, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Bunger, SERDP Office, 901 North Stuart Street, Suite 303, Arlington, VA 22203, telephone (703) 696–2126.

Dated: August 15, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–19497 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

U.S. Nuclear Command and Control System Comprehensive Review Advisory Committee

AGENCY: Department of Defense.

ACTION: Notice of meeting; Amendment.

SUMMARY: On August 11, 2008 (73 FR 46605), the Department of Defense announced a closed meeting of the U.S. Nuclear Command and Control System Comprehensive Review Advisory Committee. This notice is being published to announce changes in the time, location and agenda of the meeting.

DATES: September 3, 2008 (0830–1700) and September 4, 2008 (0800–1730).

ADDRESSES: U.S. Strategic Command Headquarters Conference Room, Offutt AFB, NB.

FOR FURTHER INFORMATION CONTACT: Mr. William L. Jones, (703) 681–8681, U.S. Nuclear Command and Control System Support Staff (NSS), Skyline 3, 5201 Leesburg Pike, Suite 500, Falls Church, VA 22041.

SUPPLEMENTARY INFORMATION:

Agenda: Sep 3, 2008: Offutt AFB/HQ USSTRATCOM—Force Execution

Time	Topic	Presenter
8:30 a.m.	NMCS Capabilities Brief	Joint Staff
9:30 a.m.	NMCS Roadmap	Joint Staff/USAF
10 a.m.	Nuclear Forces Connectivity (DC2N concept, Thin-line funding and projected capabilities)	OASD (NII)/DISA
10:30 a.m.	Oversight of NCCS Assets	OASD (NII)
11:30 a.m.	Lunch	Club
1 p.m.	Tour GOC, Air Room	STRATCOM
2 p.m.	Briefing on OPLAN	USSTRATCOM
3 p.m.	DOD Exercise Results	JS/STRATCOM
4 p.m.	Executive Session.	
5 p.m.	Adjourn.	

Agenda: Sep 4, 2008: Offutt AFB/HQ USSTRATCOM—Force Execution

Time	Topic	Presenter
8 a.m.	Tour NMCS aircraft, get capabilities brief	Crew
9 a.m.	NATO NC2 Capabilities & Procedures	EUCOM
10:30 a.m.	Integrated Tactical Warning/Attack Assessment (Modernization Plans, C2 Plans, issues, capabilities gaps).	AFSPC
11:30 a.m.	Communication Satellite Transition Plans	Air Staff
12 p.m.	Lunch.	
1 p.m.	Nuclear Technical Performance Criteria (NTPC)	J Staff by VTC
3 p.m.	National Military Command System	J Staff by VTC2
4 p.m.	POLO Hat Program (results/trends)	J Staff by VTC
5 p.m.	Executive Session.	
5:30 p.m.	Adjourn.	

Dated: August 13, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–19498 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Uniform Formulary Beneficiary Advisory Panel

AGENCY: Department of Defense, Assistant Secretary of Defense (Health Affairs).

ACTION: Notice of meeting.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended) and the Sunshine in the Government Act of 1976 (U.S.C. 552b, as amended) the Department of Defense announces the following Federal Advisory Committee Meeting of the Uniform

Formulary Beneficiary Advisory Panel (hereafter referred to as the Panel).

DATES: September 17, 2008 (8 a.m. to 4 p.m.)

ADDRESSES: Naval Heritage Center Theater, 701 Pennsylvania Avenue, NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: LtCol Thomas Bacon, Designated Federal Officer, Uniform Formulary Beneficiary Advisory Panel, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, Virginia 22041–3206, Telephone: (703) 681–2890, Fax: (703) 681–1940, e-mail address: *baprequests@tma.osd.mil*.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: The Panel will review and comment on recommendations made to the Director, TRICARE Management Activity, by the Pharmacy and Therapeutics (P&T) Committee regarding the Uniform Formulary.

Meeting Agenda: Sign-In; Welcome and Opening Remarks; Public Citizen Comments; Scheduled Therapeutic Class Reviews—Self-Monitoring Blood Glucose Systems (meters and strips); Overactive Bladder Agents; Designated Newly Approved Drugs; Panel Discussions and Vote, and comments following each therapeutic class review.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, and the availability of space this meeting is open to the public. Seating is limited and will be provided only to the first 220 people signing in. All persons must sign in legibly.

Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.155, the Department of Defense has determined that the Administrative Work Meeting (to be held prior to the public meeting) shall be closed to the public. The Under Secretary of Defense (Personnel and Readiness), in consultation with the Office of the DoD General Counsel, has determined in writing that the public interest requires that all or part of this meeting be closed to the public because they will be concerned with matters listed in Section 552b(c)(1) of title 5, United States Code.

Prior to the public meeting the Panel will conduct an Administrative Work Meeting from 7 a.m. to 7:50 a.m. to discuss administrative matters of the Panel. The Administrative Work Meeting will be held at the Naval Heritage Center Conference Room, 701 Pennsylvania Avenue, NW., Washington D.C. 20004. Pursuant to 41 CFR 102–3.160, the Administrative Work Meeting will be closed to the public.

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to the membership of the Panel at any time or in response to the stated agenda of a planned meeting. Written statements should be submitted to the Panel's Designated Federal Officer; the Designated Federal Officer's contact information can be obtained from the GSA's FACA Database—*https://www.fido.gov/facadatabase/public.asp*.

Written statements that do not pertain to the scheduled meeting of the Panel may be submitted at any time. However, if individual comments pertain to a specific topic being discussed at a planned meeting then these statements must be submitted no later than five (5) business days prior to the meeting in question. The Designated Federal Officer will review all submitted written statements and provide copies to all the committee members.

Oral Public Comments: In addition to written statements, the Panel will set aside one (1) hour for individuals or interested groups to address the Panel. To ensure consideration of their comments, individuals and interested groups should submit written statements as outlined in this notice, but if they still want to address the Panel then they will be afforded the opportunity to register to address the Panel. The Panel's Designated Federal Officer will have a ''Sign Up Roster'' available at the Panel meeting for registration on a first-come, first-serve basis. Those wishing to address the Panel will be given no more than five (5) minutes to present their comments, and at the end of the one (1) hour time period no further public comments will be accepted. Anyone who signs up to address the Panel but is unable to do so due to the time limitation may submit their comments in writing; however, they must understand that their written comments may not be reviewed prior to the Panel's deliberation. Accordingly, the Panel recommends that individuals and interested groups consider submitting written statements instead of addressing the Panel.

Dated: August 15, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–19503 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2008–OS–0089]

Privacy Act of 1974; System of Records

AGENCY: Office of the Inspector General, DoD.

ACTION: Notice to amend two systems of records.

SUMMARY: The Office of the Inspector General (OIG) is amending two systems of records notices in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on September 22, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to Chief, FOIA/PA Office, Inspector General, Department of Defense, 400 Army Navy Drive, Room 201, Arlington, VA 22202–4704.

FOR FURTHER INFORMATION CONTACT: Mr. Keith Mastromichalis at (703) 604–8723.

SUPPLEMENTARY INFORMATION: The Office of the Inspector General (OIG) systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the records systems being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: August 15, 2008.

Patricia Toppings,

Federal Register Liaison Officer, Department of Defense.

CIG–9

SYSTEM NAME:

Security Management and Access Files (May 9, 2003, 68 FR 24932).

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''Automated Security Administration System Records.''

* * * * *

SYSTEMS LOCATION:

Delete entry and replace with ''Office of Security, Office of Administration & Management, Office of the Inspector General of the Department of Defense, 400 Army Navy Drive, Arlington, VA 22202–4704.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Director, Office of Security, Office of Administration & Management, Office of the Inspector General of the Department of Defense, 400 Army Navy Drive, Arlington, VA 22202–4704.''

* * * * *

CIG–09

SYSTEM NAME:

Automated Security Administration System Records.

SYSTEM LOCATION:

Office of Security, Office of Administration & Management, Office of the Inspector General of the Department of Defense, 400 Army Navy Drive, Arlington, VA 22202–4704.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All civilian, contractor, and military personnel of the Office of the Inspector General of the Department of Defense (OIG DoD) who have been found eligible for employment/assignment, and who qualify and are eligible to occupy sensitive positions, perform sensitive duties, or for access to classified information.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records of each individual associated with personnel security functions. These records also include, but are not limited to, individual's name; Social Security Number (SSN); date and place of birth; current employment status; duty address; security training; an individual's qualification and eligibility to occupy sensitive positions, perform sensitive duties, or for access to classified information; certificates of clearance; security violations; identification badge records, courier authorizations, and access control records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

E.O. 10450, Security Requirements for Government Employment, as amended; DoD 5200.2–R, DoD Personnel Security Program Regulation; and E.O. 9397 (SSN).

PURPOSE(S):

This record system is used by OIG Management officials to control the number of, and level of, sensitive positions; identify personnel assigned to these positions; and to determine whether personnel have been granted a clearance and the level of such clearance or access authorized.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Information on the clearance/eligibility status of individuals may be provided to the appropriate clearance access officials of other agencies when necessary in the course of official business. Certifications of clearance are issued to officials of other agencies when necessary in the course of official business.

The DoD ''Blanket Routine Uses'' set forth at the beginning of the OIG's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records maintained in folders; computer printouts and automated data base files.

RETRIEVABILITY:

Information is retrieved by individual's name, Social Security Number (SSN), and date and place of birth.

SAFEGUARDS:

Access to building is protected by guards requiring positive identification for admission. Access to computerized files is password protected, and is limited to authorized users having a need-to-know in the performance of their official duties.

RETENTION AND DISPOSAL:

Paper records are destroyed when superseded, obsolete or upon notification of death, or no later than 5 years after transfer or separation of the individual.

Electronic records are deleted after dissemination, revision or updating is complete, or within 180 days after the paper copy has been produced.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Security, Office of Administration & Management, Office of the Inspector General of the Department of Defense, 400 Army Navy Drive, Arlington, VA 22202–4704.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Chief, Freedom of Information Act/Privacy Act Office, 400 Army Navy Drive, Arlington, VA 22202–4704.

Written request should contain the individual's full name, Social Security Number (SSN), date and place of birth, current address and telephone numbers of the individual requester.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Chief, Freedom of Information Act/Privacy Act Office, 400 Army Navy Drive, Arlington, VA 22202–4704.

Written request should contain the individual's full name, Social Security Number (SSN), date and place of birth, current address and telephone numbers of the individual requester.

CONTESTING RECORD PROCEDURES:

The OIG's rules for accessing records and for contesting contents and appealing initial agency determinations are published in 32 CFR part 312 or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Certificates of clearance and/or record of personnel security investigations which are completed during a review of reports of investigations conducted by the Department of Defense and other Federal investigative organizations. Also, personnel security files are maintained on individuals.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

CIG–22

SYSTEM NAME:

OIG DoD Badge and Credentials (October 14, 2003, 68 FR 59165).

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''Identicard Systems Records.''

SYSTEMS LOCATION:

Delete entry and replace with ''Office of Security, Office of Administration & Management, Office of the Inspector General of the Department of Defense, 400 Army Navy Drive, Arlington, VA 22202–4704.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Director, Office of Security, Office of Administration & Management, Office of the Inspector General of the Department of Defense, 400 Army Navy Drive, Arlington, VA 22202–4704.''

* * * * *

CIG–22

SYSTEM NAME:

Identicard Systems Records.

SYSTEM LOCATION:

Office of Security, Office of Administration & Management, Office of the Inspector General of the Department of Defense, 400 Army Navy Drive, Arlington, VA 22202–4704.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are granted/issued an OIG DoD badge and/or credential, to include all accredited OIG DoD Special Agents.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records containing personal information consisting of an individual's name, Social Security Number (SSN), letters of authorization to issue badge and/or credential, badge and credential receipts, badge listing, badge and/or credential inspection reports, and badge and/or credential number assigned to OIG DoD employee and/or Special Agent.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Inspector General Act of 1978, (Pub. L. 95–452), as amended; 18 U.S.C. 499, Military naval or official passes; 18 U.S.C. 506, Seals of the department or agencies; 18 U.S.C. 701, Official badges, identification cards, other insignia; 10 U.S.C. 133, Secretary of Defense; DoD Directive 5106.1, Inspector General of the Department of Defense; OIG DoD DCIS Special Agents Manual; OIG Instruction 1000.1, Employee Identification Program; and E.O. 9397 (SSN).

PURPOSE(S):

To issue and control the badge and/or credential assigned to an OIG DoD employee and/or Special Agent. Used only by OIG DoD to identify specifically to which individual each badge and/or credential is assigned, to provide for orderly update of badge and/or credentials and to ensure turn in of badge and/or credentials whenever accreditation is terminated.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD ''Blanket Routine Uses'' set forth at the beginning of the OIG's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folder and electronic storage media.

RETRIEVABILITY:

Retrieved by individual's name.

SAFEGUARDS:

Paper and electronic records are stored in locked filing cabinets and stored in a limited access area. Building is locked and guarded during non-duty hours. Only those individuals with a need to know access the records. Access to computer records are password protected.

RETENTION AND DISPOSAL:

Paper records and computer disks are to be retained until completion of the overall validation process and data analysis, and then destroyed. When badge and credentials are turned in, records are destroyed 3 months after turn in.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Security, Office of Administration & Management, Office of the Inspector General of the Department of Defense, 400 Army Navy Drive, Arlington, VA 22202–4704.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address a written request to the Chief, Freedom of Information Act/Privacy Act Office, 400 Army Navy Drive, Arlington, VA 22202–4704.

Written request should contain the individual's full name, current address, telephone number, and the request must be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking to access information about themselves contained in this system of records should address a written request to the Chief, Freedom of Information Act/Privacy Act Office, 400 Army Navy Drive, Arlington, VA 22202–4704.

Written request should contain the individual's full name, current address, telephone number, and the request must be signed.

CONTESTING RECORD PROCEDURES:

The OIG's rules for accessing records and for contesting contents and appealing initial agency determinations are published in 32 CFR part 312 or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is obtained from individual personnel records and issued badge and credentials.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–19507 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2008–OS–0086]

Privacy Act of 1974; System of Records

AGENCY: Office of the Inspector General, DoD.

ACTION: Notice to amend three systems of records.

SUMMARY: The Office of the Inspector General (OIG) is amending three systems of records notices in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on September 22, 2008 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to Chief, FOIA/PA Office, Inspector General, Department of Defense, 400 Army Navy Drive, Room 201, Arlington, VA 22202–4704.

FOR FURTHER INFORMATION CONTACT: Mr. Keith Mastromichalis at (703) 604–8723.

SUPPLEMENTARY INFORMATION: The Office of the Inspector General (OIG) systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the records systems being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within

the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: August 15, 2008.

Patricia Toppings,

Federal Register Liaison Officer, Department of Defense.

CIG–17

SYSTEM NAME:

Voluntary Leave Transfer Program Records (June 5, 2006, 71 FR 32309).

CHANGES:

* * * * *

SYSTEMS LOCATION:

Delete entry and replace with ''Human Capital Advisory Services, Department of Defense Office of the Inspector General, 400 Army Navy Drive, Arlington, VA 22202–4704.''

* * * * *

PURPOSE(S):

Delete entry and replace with ''The file is used to managing the Department of Defense Office of the Inspector General, Voluntary Leave Transfer Program. The recipient's name, position data and organization are published internally for passive solicitation purposes. The Social Security Number is sought to effectuate the transfer of leave from the donor's account to the recipient's account.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace ''Human Capital Advisory Services, Department of Defense Office of the Inspector General, 400 Army Navy Drive, Arlington, VA 22202–4704.''

* * * * *

CIG–17

SYSTEM NAME:

Voluntary Leave Transfer Program Records.

SYSTEM LOCATION:

Human Capital Advisory Services, Department of Defense Office of the Inspector General, 400 Army Navy Drive, Arlington, VA 22202–4704.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have volunteered to participate in the leave transfer program as either a donor or a recipient.

CATEGORIES OF RECORDS IN THE SYSTEM:

Leave recipient records contain the individual's name, organization, office telephone number, Social Security Number (SSN), position title, grade, pay level, leave balances, number of hours requested, brief description of the medical or personal hardship which qualifies the individual for inclusion in the program, and the status of that hardship.

The file may also contain medical or physician certifications and agency approvals or denials.

Donor records include the individual's name, organization, office telephone number, Social Security Number (SSN), position title, grade, and pay level, leave balances, number of hours donated and the name of the designated recipient.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 6331 *et seq.*, Leave; 5 CFR part 630, Absence and Leave; IG Instruction 1424.630, Leave Administration Policy and Procedures; and E.O. 9397 (SSN).

PURPOSE(S):

The file is used to managing the Department of Defense Office of the Inspector General, Voluntary Leave Transfer Program. The recipient's name, position data and organization are published internally for passive solicitation purposes. The Social Security Number is sought to effectuate the transfer of leave from the donor's account to the recipient's account.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(a)(b)(3) as follows:

To the Department of Labor in connection with a claim filed by an employee for compensation due to a job-connected injury or illness; where leave donor and leave recipient are employed by different Federal agencies, to the personnel and pay offices of the Federal agency involved to effectuate the leave transfer.

The DoD ''Blanket Routine Uses'' set forth at the beginning of the OIG's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Records are retrieved by name or Social Security Number (SSN).

SAFEGUARDS:

Records are accessed by custodian of the records or by persons responsible for servicing the record system in performance of their official duties. Records are stored in locked cabinets or rooms and are controlled by personnel screening and computer software.

RETENTION AND DISPOSAL:

Records are destroyed one year after the end of the year in which the file is closed.

SYSTEM MANAGER(S) AND ADDRESS:

Human Capital Advisory Services, Department of Defense Office of the Inspector General, 400 Army Navy Drive, Arlington, VA 22202–4704.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Freedom of Information Act Requester Service Center/Privacy Act Office, 400 Army Navy Drive, Arlington, VA 22202–4704.

Individual should provide full name and Social Security Number (SSN).

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquires to the Freedom of Information Act Requester Service Center/Privacy Act Office, 400 Army Navy Drive, Arlington, VA 22202–4704.

Individual should provide full name and Social Security Number (SSN).

CONTESTING RECORD PROCEDURES:

The OIG's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in 32 CFR part 312 and may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is provided primarily by the record subject; however, some data may be obtained from personnel and leave records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

CIG–18

SYSTEM NAME:

Grievance Records (June 5, 2006, 71 FR 32310).

CHANGES:

* * * * *

SYSTEMS LOCATION:

Delete entry and replace with ''Records are maintained by Department of Defense Office of the Inspector General, Human Capital Advisory Services, Workforce Relations Division, 400 Army Navy Drive, Suite 115, Arlington, VA 22202–4704.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Human Capital Advisory Services, Department of Defense Office of the Inspector General, 400 Army Navy Drive, Arlington, VA 22202–4704.''

* * * * *

CIG 18

SYSTEM NAME:

Grievance Records.

SYSTEM LOCATION:

Records are maintained by Department of Defense Office of the Inspector General, Human Capital Advisory Services, Workforce Relations Division, 400 Army Navy Drive, Suite 115, Arlington, VA 22202–4704.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current or former Inspector General, Department of Defense employees who have submitted grievances in accordance with 5 CFR Part 771, DoD Directive 1400.25–M Subchapter 771 and DoD Inspector General Instruction 1400.5.

CATEGORIES OF RECORDS IN THE SYSTEM:

The case files contain all documents related to grievances including reports of interviews and hearings, examiner's findings and recommendations, copy of the original and final decision, and related correspondence and exhibits.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 2302, Prohibited personnel practices; 5 U.S.C. 7121, Grievance procedures; 5 CFR part 771; DoD 1400.25–M, Subchapter 771, Administrative Grievance System; DoD Inspector General Instruction 1400.5; and E.O. 9397 (SSN).

PURPOSE(S):

The information will be used by the Department of Defense Office of the Inspector General to control and process grievances; to investigate the allegations; conduct interviews; and render the final decision.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(a)(b)(3) as follows:

To disclose information to any source from which additional information is requested in the course of processing a grievance, to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, and identify the type of information requested.

To disclose in response to a request for discovery or for appearance of a witness, information that is relevant to the subject matter involved in a pending judicial or administrative proceeding.

To provide information to officials of labor organization reorganized under the Civil Service Reform Act when relevant and necessary to their duties, exclusive representation concerning personnel policies, practices, and matter affecting work conditions.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in paper form.

RETRIEVABILITY:

Records are retrieved by names of the individuals on whom the records are maintained.

SAFEGUARDS:

Records are maintained in locked metal file cabinets, to which only DoD OIG authorized personnel have access.

RETENTION AND DISPOSAL:

Records are destroyed four years after the case is closed.

SYSTEM MANAGER(S) AND ADDRESS:

Human Capital Advisory Services, Department of Defense Office of the Inspector General, 400 Army Navy Drive, Arlington, VA 22202–4704.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Freedom of Information Act Requester Service Center/Privacy Act Office, 400 Army Navy Drive, Arlington, VA 22202–4704.

Written requests for information should include the full name.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquires to the Freedom of Information Act Requester Service Center/Privacy Act Office, 400 Army Navy Drive, Arlington, VA 22202–4704.

Written requests for information should include the full name.

CONTESTING RECORD PROCEDURES:

The OIG's rules for accessing records and for contesting contents and appealing initial agency determinations are published in 32 CFR part 312 and may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is provided by the individual on whom the record is maintained; by testimony of witnesses; by Agency officials; or from related correspondence from organizations or persons.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

CIG–25

SYSTEM NAME:

Alternate Worksite Records (January 8, 2007, 72 FR 728).

CHANGES:

* * * * *

SYSTEMS LOCATION:

Delete entry replace with ''Primary location: Human Capital Advisory Services (Workforce Relations Division), Department of Defense Office of the Inspector General, 400 Army Navy Drive, Suite 115, Arlington, VA 22202–4704.

SECONDARY LOCATIONS:

Defense Criminal Investigative Service Field Offices, Resident Agencies, Posts of Duty and Audit Field Offices

Official mailing addresses are published as an appendix to the OIG's compilation of systems of records notices.''

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEMS:

Delete entry and replace with ''Records in the systems include participant name; position title; occupation and pay band, performance evaluation rating; official duty station address and telephone numbers; type of telework; date telework agreement received and approved; alternative worksite address and telephone numbers; telework eligibility forms; telework agreement forms; telework home and security checklists; whether government equipment is assigned; telework arrangement checkout checklists; telework centers reimbursement sheets; and regular and

recurring telework memorandums; and any other miscellaneous documents supporting telework.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Assistant Director, Human Capital Advisory Services (Workforce Relations), 400 Army Navy Drive, Suite 115, Arlington, VA 22202–4704.''

* * * * *

CIG–25

SYSTEM NAME:

Primary location: Human Capital Advisory Service (Workforce Relations Division), Department of Defense Office of the Inspector General, 400 Army Navy Drive, Suite 115, Arlington, VA 22202–4704.

SECONDARY LOCATIONS:

Defense Criminal Investigative Service Field Offices, Resident Agencies, and Posts of Duty.

Official mailing addresses are published as an appendix to the OIG's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Civilian employees who participate in the Telework program operated by OIG.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in the systems include participant name; position title; occupation and pay band, performance evaluation rating; official duty station address and telephone numbers; type of telework; date telework agreement received and approved; alternative worksite address and telephone numbers; telework eligibility forms; telework agreement forms; telework home and security checklists; whether government equipment is assigned; telework arrangement checkout checklists; telework centers reimbursement sheets; and regular and recurring telework memorandums; and any other miscellaneous documents supporting telework.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Law 106–346, Section 359 of October 23, 2000; Under Secretary of Defense (Personnel and Readiness) Memorandum dated October 22, 2001, ''Department of Defense Telework Policy and Guide for Civilian Employees,'' and DoD Directive 1035.1 Telework Policy for Department of Defense.

PURPOSE(S):

Records are used by supervisor and program coordinators for purposes of managing, evaluating, and reporting OIG telework program activity.

Portions of the files may be for determining equipment and software needs; for ensuring appropriate technical safeguards are in use at alternative work sites; and for evaluating and mitigating vulnerabilities associated with connecting to OIG computer systems from remote locations and to validate and reimburse participants for costs associated with telephone use.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(b)(3) as follows:

To the Department of Labor when an employee is injured while working at the alternative worksite.

The DoD ''Blanket Routine Uses'' set forth at the beginning of OIG's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and electronic storage media.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Records are maintained in areas accessible only to DoD OIG personnel and is limited to those who require the records in the performance of their official duties. Paper Records are secured in locked cabinets during non-duty hours and access to electronic records is restricted by the use of passwords.

RETENTION AND DISPOSAL:

Records are destroyed (shredded) within 1 year after employee's participation in the program ends.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Human Capital Advisory Services (Workforce Relations), 400 Army Navy Drive, Suite 115, Arlington, VA 22202–4704.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether records about themselves is contained in this system of records should address written inquiries to the Freedom of Information Act Requester Service Center/Privacy Act Office, Department of Defense, Office of the Inspector General, 400 Army Navy Dr, Arlington VA 22202–4704.

The request should contain the individual's full name, address, and telephone number. These items are necessary for the retrieval of information. Requests submitted on behalf of other persons must include their written authorization.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Freedom of Information Act Requester Service Center/Privacy Act Office, Department of Defense, Office of the Inspector General, 400 Army Navy Dr, Arlington VA 22202–4704.

The request should contain the individual's full name, address, and telephone number. These items are necessary for the retrieval of information. Requests submitted on behalf of other persons must include their written authorization.

CONTESTING RECORD PROCEDURES:

The OIG's rules for accessing records and for contesting contents and appealing initial agency determinations are published in 32 CFR part 312 or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

By participants and supervisors.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–19508 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2008–0017]

Privacy Act of 1974; System of Records

AGENCY: Department of Air Force.

ACTION: Notice to Amend a System of Records.

SUMMARY: The Department of Air Force proposes to amend a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The changes will be effective on September 22, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Air Force Privacy Act Officer, Office of

Warfighting Integration and Chief Information Officer, SAF/XCISI, 1800 Air Force Pentagon, Suite 220, Washington, DC 20330–1800.

FOR FURTHER INFORMATION CONTACT: Mr. Leroy Jones at (703) 696–6488.

SUPPLEMENTARY INFORMATION: The Department of the Air Force systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the record system being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: August 15, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

F036 AETC J

SYSTEM NAME:

College Scholarship Program (CSP) (July 7, 2008, 73 FR 38411).

CHANGES:

Change System ID to ''F036 AETC X''.

* * * * *

F036 AETC X

SYSTEM NAME:

College Scholarship Program (CSP).

SYSTEM LOCATION:

Central records maintained at the College Scholarship Program (CSP), HQ AFROTC/RRUC, 551 East Maxwell Boulevard, Maxwell Air Force Base, AL 36112–6106.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

High school students or graduates who apply for the CSP.

CATEGORIES OF RECORDS IN THE SYSTEM:

Air Force Reserve Officer Training Corp (AFROTC) administrative unit; applicant's address; AFROTC detachment located at the educational institution to be attended by the applicant; AFROTC detachment which the applicant desires to attend; Air Force Junior Reserve Officer Training Corp (AFJROTC) unit attended by applicant; college entrance examination board scores; applicant's class standing and size of class; applicant's disqualification causes; personal interview actions and associated waivers as required; applicant's medical status; applicant's full name; AFROTC program qualification; applicant's medical remedial requirements; applicant's scholarship status; applicant's Social Security Number (SSN); applicant's test qualification; civil air patrol wing attended; applicant's high school and address; applicant's high school placement; applicant's grade point average; applicant's telephone number; applicant's date of birth; applicant's statement of understanding and intent; medical testing facility; AFROTC area admission counselor's areas of responsibilities; applicant's scholarship choices; AFROTC CSP scholarship selection board results; applicant's designated scholarship; civil involvement information and associated waivers as required; name of educational institution to be attended by applicant; applicant's high school principal evaluation; AFJROTC instructor evaluation of a cadet; English teacher's evaluation; Math teacher's evaluation; Science teacher's evaluation; high school transcripts; application forms. Computer generated summary data posted on the Air Force Officer Accessions Training School (AFOATS) restricted Web site viewed only by AFROTC detachments.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 2107, Financial Assistance Program for Specially Selected Members; Air Force Instruction 36–2011, Air Force Reserve Officer Training Corps; Executive Order 9897; and E.O. 9397 (SSN).

PURPOSE(S):

Used by AFROTC scholarship program office and AFROTC detachments for processing and awarding of CSP scholarships; counseling applicants concerning application difficulties and problems; investigatory material compiled to determine suitability, eligibility and selection for a scholarship, and the recruiting of applicants into the AFROTC program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Department of Defense as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The ''Blanket Routine Uses'' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders, visible file binders/cabinets, and electronic storage media.

RETRIEVABILITY:

By name and Social Security Number (SSN).

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets. Those in computer storage devices are protected by computer system software. All information is sent out through the U.S. Postal Service.

RETENTION AND DISPOSAL:

Destroy after 1 year or when no longer needed whichever is sooner. Destroy by tearing into pieces, shredding, pulping, macerating, or burning. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Mr. Jack Sanders, Chief, College Scholarship Program, HQ AFROTC/RRUC, 551 East Maxwell Blvd., Maxwell Air Force Base, AL 36112–6106.

NOTIFICATION PROCEDURE:

Applicants seeking to determine whether information about themselves is contained in this system can address written requests to or visit the Chief, College Scholarship Program, HQ AFROTC/RRUC, 551 East Maxwell Boulevard, Maxwell Air Force Base, AL 36112–6106 or to the AFROTC Detachment Commander at location of assignment.

Applicants must provide their full name, military-applicant status, and Social Security Number or military service number.

RECORD ACCESS PROCEDURES:

Applicants seeking access to information about themselves from CSP records can obtain assistance by writing to or visiting the Chief, College Scholarship Program, HQ AFROTC/RRUC, 551 East Maxwell Blvd., Maxwell Air Force Base, AL 36112–6106 or to the AFROTC Detachment Commander at location of assignment.

Applicants must provide their full name, military-applicant status, and

Social Security Number or military service number.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 33–332; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from educational institutions, automated system interfaces, police and investigating officers and from source documents such as reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Portions of this system which fall within 5 U.S.C. 552a(k)(5) are exempt from the following provisions of Title 5 U.S.C. 552a: Sections (c)(3); (d); (e)(4), (g), (h), and (f) of the Act, but only to the extent that disclosure would reveal the identity of a confidential source.

An exemption rule for this record system has been promulgated in accordance with the requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) and published in 32 CFR part 806b. For additional information contact the system manager.

[FR Doc. E8–19504 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

Army Education Advisory Committee Meeting

AGENCY: Department of the Army, DoD.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (U.S.C. 552b, as amended) and 41 Code of the Federal Regulations (CFR) 102–3. 140 through 160, the Department of the Army announces the following committee meeting:

Name of Committee: Army Education Advisory Committee.

Date of Meeting: September 17, 2008.

Time of Meeting: 0830–1500, September 17, 2008.

Place of Meeting: Cadet Command Headquarters, 55 Pratt Road, Building 56, Commander's Conference Room, Ft Monroe, VA.

Interested persons may submit a written statement for consideration by the Army Education Advisory Committee. Individuals submitting a written statement must submit their statement to the Designated Federal Official at the address detailed below, at any point, however, if a written statement is not received at least 10 calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the Army Education Advisory Committee. The Designated Federal Official will review all timely submissions with the Army Education Advisory Committee Chairperson, and ensure they are provided to members of the Army Education Advisory Committee before the meeting that is the subject of this notice.

FOR FURTHER INFORMATION CONTACT: For information please contact Mr. Wayne Joyner at *albert.wayne.joyner@us.army.mil* or (757) 788–5890.

SUPPLEMENTARY INFORMATION: *Proposed Agenda:* The Army Education Advisory Committee will meet on September 17, 2008, Cadet Command Headquarters, Building 56, Ft Monroe, VA. Purpose of the meeting is to allow review, discussions, and deliberations of actions and recommendations from five subcommittees: Defense Language Institute Foreign Language Center, Command and General Staff College Board of Visitors, Army War College Board of Visitors, Distance Learning/ Training Technology Applications Subcommittee, and the Reserve Officer Training Corps Subcommittee. Approved recommendations will be forwarded to the Office of the Administrative Assistant, Secretary of the Army, the appropriate Subcommittee's Alternate Designated Federal Official (ADFO), and the Subcommittee's decision maker.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. E8–19486 Filed 8–21–08; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2008–OS–0088]

Privacy Act of 1974; Systems of Records

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice to delete a system of records.

SUMMARY: The Defense Logistics Agency is deleting a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on September 22, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Headquarters, Defense Logistics Agency, ATTN: DP, 8725 John J. Kingman Road, Stop 2533, Fort Belvoir, VA 22060–6221.

FOR FURTHER INFORMATION CONTACT: Ms. Jody Sinkler at (703) 767–5045.

SUPPLEMENTARY INFORMATION: The Defense Logistics Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The Defense Logistics Agency proposes to delete a system of records notice from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: August 15, 2008.

Patricia Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

S100.90

SYSTEM NAME:

Attorney Personnel Information and Applicant Files (May 13, 2004, 69 FR 26558).

REASON:

Records are covered by OPM Government-wide Privacy Act systems of records notices.

[FR Doc. E8–19509 Filed 8–21–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Public Scoping Meetings for Update of the Water Control Manual for the Alabama-Coosa-Tallapoosa River Basin in Alabama and Georgia

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Supplement to Notice of Intent.

SUMMARY: The U.S. Army Corps of Engineers (Corps), Mobile District, issued a Notice of Intent (NOI) in the **Federal Register** (72 FR 63561), published on November 9, 2007,

describing the preparation of a Draft Environmental Impact Statement (EIS), as required by the National Environmental Policy Act (NEPA), to address the proposed update of the Water Control Manual (WCM) for the Alabama-Coosa-Tallapoosa (ACT) River Basin.

The Corps will hold four public scoping meetings during the month of September as part of its review and update of the WCM for the ACT River Basin. The public is invited to attend the scoping meetings which will provide information on the WCM update process and afford the opportunity to receive input from the public about their issues and concerns regarding that process. All four public meetings will be held using an open house format, allowing time for participants to review specific information and to provide comments to the resource staff attending the meeting.

DATES: The meeting dates are:

1. September 15, 2008, 5 p.m.–8 p.m (EDT),Cobb County, GA.
2. September 16, 2008, 5 p.m.–8 p.m. (EDT), Rome, GA.
3. September 17, 2008, 5 p.m.–8 p.m. (CDT), Gadsden, AL.
4. September 18, 2008, 5 p.m.–8 p.m. (CDT), Montgomery, AL.

ADDRESSES: The meeting locations are:

1. Cobb County, GA—Ben Robertson Community Center, Banquet Room, 2753 Watts Drive, Kennesaw, GA 30144, (770) 422–9714.
2. Rome, GA—The Forum Civic Center, Riverwalk Ballroom, 2 Government Plaza, Rome, GA 30161, (706) 291–5281.
3. Gadsden, AL—Senior Center Auditorium, 623 Broad Street, Gadsden, AL 35901, (256) 549–4740
4. Montgomery, AL—Quality Inn (Old Governors House), Alabama Room, 2705 East South Blvd., Montgomery, AL 36116, (334) 288–2800.

FOR FURTHER INFORMATION CONTACT: Questions about the manual update or NEPA process can be answered by: Mr. Chuck Sumner, Environment and Resources Branch, Planning and Environmental Division, U.S. Army Engineer District—Mobile, Post Office Box 2288, Mobile, AL 36628–0001; Telephone (251) 694–3857; or delivered by electronic facsimile at (251) 694–3815; or e-mail: *lewis.c.sumner@usace.army.mil*. You may also request to be included on the mailing list for public distribution of notices, meeting announcements and documents.

SUPPLEMENTARY INFORMATION: Additional information on the ACT River Basin and the Water Control Manual Update process will be posted on the Mobile District Web page as it becomes available: *http://www.sam.usace.army.mil*.

Date: August 15, 2008.

Byron G. Jorns,

Colonel, Corps of Engineers, District Commander.

[FR Doc. E8–19487 Filed 8–21–08; 8:45 am]

BILLING CODE 3710–CR–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 22, 2008.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name,'' *e.g.*, ''Upward Bound Evaluation'']. Persons submitting comments electronically should not submit paper copies.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.*, new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: August 18, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Elementary and Secondary Education

Type of Review: Extension.

Title: Annual Report of Children in State Agency and Locally Operated Institutions for Neglected and Delinquent Children.

Frequency: Annually.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 3,052.

Burden Hours: 4,224.

Abstract: An annual survey is conducted to collect data on (1) the number of children enrolled in educational programs of State-operated institutions for neglected or delinquent (N or D) children, community day programs for N or D children, and adult correctional institutions and (2) the October caseload of N or D children in local institutions.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3694. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E8–19482 Filed 8–21–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Extension of Project Period and Waiver for the Puerto Rico State Technical Assistance (TA) Project To Improve Services and Results for Children Who Are Deaf-Blind

AGENCY: Office of Special Education Programs, Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of proposed extension of project period and waiver for the Puerto Rico State Technical Assistance (TA) Project to Improve Services and Results for Children Who Are Deaf-Blind.

SUMMARY: The Secretary proposes to waive the requirements in the Education Department General Administrative Regulations (EDGAR), in 34 CFR 75.250 and 75.261(a), respectively, that generally prohibit project periods exceeding five years and extensions of project periods involving the obligation of additional Federal funds. This extension of project period and waiver will enable the currently funded Puerto Rico State TA Project to Improve Services and Results for Children Who Are Deaf-Blind to receive funding from October 1, 2008 through September 30, 2009.

DATES: We must receive your comments on or before September 8, 2008.

ADDRESSES: Address all comments concerning this proposed extension and waiver to Anne Smith, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4086, Potomac Center Plaza, Washington, DC 20202–2641. Telephone: (202) 245–7529. If you prefer to send your comments through the Internet, use the following address: *anne.smith@ed.gov.*

FOR FURTHER INFORMATION CONTACT: Anne Smith. Telephone: (202) 245–7529.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339. Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION:

Invitation to Comment

We invite you to submit comments regarding this proposed extension of project period and waiver.

During and after the comment period, you may inspect all public comments about this proposed extension of project period and waiver in Room 4086, Potomac Center Plaza, 550 12th Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed extension of project period and waiver. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

The Department published a notice in the **Federal Register** on July 3, 2003 (68 FR 39902), inviting applications for awards for fiscal year (FY) 2003. Based on that notice, the Department made 48 awards, including one award for a period of 60 months to the Puerto Rico Department of Education, in order to build the capacity of the State, parents, and professionals to improve outcomes for children and young adults who are deaf-blind and their families by providing TA, information, and training on early intervention, special education, related services, and transitional services. The Department published a notice inviting applications for awards for FY 2008 on March 25, 2008 (73 FR 15444). The Puerto Rico Department of Education submitted an application, but the budget request was above the maximum amount allocated to them, and, therefore, the application was ineligible for review. Given the severity of deaf-blindness and the low incidence of this population, it is important to ensure continuation of State TA services for children who are deaf-blind in Puerto Rico. Therefore, the Department proposes to extend the current grant to the Puerto Rico Department of Education (H326C030042) for a sixth year and award an additional $65,000 to that agency. The Department also intends to announce a competition to permit Puerto Rico to apply for four additional years of funding. The Puerto Rico Department of Education Deaf-Blind TA project has demonstrated significant progress in providing TA services to families, educators, and other service providers since it was funded in 2003. The Puerto Rico Department of Education's current project period for its Deaf-Blind TA Project is scheduled to end on September 30, 2008. Deaf-blindness is a severe and complex disability. In order to ensure that continued TA is available to assist Puerto Rican families, educators, and other professionals who work with children who are deaf-blind, the Secretary proposes to waive the requirements in 34 CFR 75.250 and 75.261(a) and proposes to issue a continuation award to the existing grantee for an additional twelve-month period.

The Puerto Rico Department of Education will continue to build the capacity of the State, parents, and professionals to improve outcomes for children and young adults who are deaf-blind and their families by providing TA, information, and training on early intervention, special education, related services, and transitional services.

Regulatory Flexibility Act Certification

The Secretary certifies that the proposed extension of the project period and waiver will not have a significant economic impact on a substantial number of small entities. The only entity that would be affected is the Puerto Rico Department of Education.

Paperwork Reduction Act of 1995

This proposed extension of project period and waiver does not contain any information collection requirements.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Electronic Access to This Document:

You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: August 18, 2008.

Tracy R. Justesen,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. E8–19563 Filed 8–21–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 12540–002; 12545–002; 12549–002]

Hydrodynamics, Inc.; Notice of Applications Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Terms and Conditions, Recommendations, and Prescriptions

August 14, 2008.

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection.

a. *Type of Application:* Minor unconstructed projects.

b. *Projects Nos.:* 12540–002, 12545–002, and 12549–002.

c. *Date filed:* March 31, 2008.

d. *Applicant:* Hydrodynamics, Inc.

e. *Name of Projects:* Woods, Johnson, and A–Drop.

f. *Location:* On the Greenfields Main Canal and the Greenfields South Canal, parts of the U. S. Bureau of Reclamation's existing Sun River Irrigation Project, in Cascade and Teton Counties, Montana, near Fairfield, Montana.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r)

h. *Applicant Contact:* Roger Kirk, Hydrodynamics, Inc., P.O. Box 1136, Bozeman, MT 59771, (406) 587–5086.

i. *FERC Contact:* Dianne Rodman, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426; telephone (202) 502–6077 or by e-mail at *dianne.rodman@ferc.gov.*

j. *Deadline for filing motions to intervene and protests, comments, terms and conditions, recommendations, and prescriptions:* 60 days from the issuance of this notice. All reply comments must be filed with the Commission within 105 days from the date of this notice.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Motions to intervene, protests, comments, terms and conditions, recommendations, and prescriptions may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

k. The applications have been accepted for filing and are now ready for environmental analysis.

l. The proposed Woods Project would be built at the Greenfields Main Canal's Woods drop structure. The applicant proposes to construct: (1) An inflatable weir spanning the full width of the canal; (2) an intake structure with trash rack and radial gate or stop-log shut off; (3) a buried, 72-inch-diameter, 750-foot-long steel or polyethylene penstock; (4) a powerhouse containing one Francis or propeller (Reaction) turbine and one generator with a rated output of 900 kilowatts (kW); (5) a tailrace returning flows to the canal; (6) a switchyard; and (7) a 376-foot-long, 69-kilovolt (kV) transmission line interconnecting with an existing powerline. Average annual generation would be 2.2 gigawatt-hours (GWh).

The proposed Johnson Project would be built at the Greenfields South Canal's Johnson drop structure. The applicant proposes to construct: (1) An inflatable weir spanning the width of the canal; (2) an intake structure with trash rack and radial gate or stop-log shut off; (3) a buried, 60-inch-diameter, 900-foot-long steel or polyethylene penstock; (4) a powerhouse containing one Francis or propeller (Reaction) turbine and one generator with a rated output of 700 kW; (5) a tailrace returning flows to the canal; (6) a switchyard; (7) a 1,024-foot-long, 69-kV transmission line interconnecting with an existing powerline; and (8) a powerhouse access road. Average annual generation would be 1.7 GWh.

The proposed A–Drop Project would be built at the Greenfields Main Canal's Greenfield drop structure. The applicant proposes to construct: (1) An inflatable weir spanning the width of the canal; (2) an intake structure with trash rack and radial gate or stop-log shut off; (3) a buried, 96-inch-diameter, 830-foot-long steel or polyethylene penstock; (4) a powerhouse containing one Francis or propeller (Reaction) turbine and one generator with a rated output of 1,000 kW; (5) a tailrace returning flows to the canal; (6) a switchyard; (7) a buried 144-foot-long, 12-kV transmission line interconnecting with an existing powerline; and (8) an approximately 730-foot-long powerhouse access road. Average annual generation would be 2.5 GWh.

m. Copies of the applications are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits, in the docket number field to access each of the documents. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. Copies are also available for inspection and reproduction at the address in item h above.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant named in this public notice.

Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all

protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceedings. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) Bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''COMMENTS'', ''REPLY COMMENTS'', ''RECOMMENDATIONS'', ''TERMS AND CONDITIONS'', or ''PRESCRIPTIONS''; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the applications directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to these applications must be accompanied by proof of service on all persons listed in the service lists prepared by the Commission in these proceedings, in accordance with 18 CFR 4.34(b) and 385.2010.

o. A license applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification(s); (2) a copy of the request(s) for certification, including proof of the date on which the certifying agency received the request(s); or (3) evidence of waiver(s) of water quality certification.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–19471 Filed 8–21–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12548–002]

Hydrodynamics, Inc.; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Terms and Conditions, Recommendations, and Prescriptions

August 14, 2008.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Minor unconstructed project.

b. *Project No.:* 12548–002.

c. *Date filed:* April 1, 2008.

d. *Applicant:* Hydrodynamics, Inc.

e. *Name of Project:* Greenfield.

f. *Location:* On the Greenfields Main Canal, part of the U.S. Bureau of Reclamation's existing Sun River Irrigation Project, in Teton County, Montana, near Fairfield, Montana.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Roger Kirk, Hydrodynamics, Inc., P.O. Box 1136, Bozeman, MT 59771, (406) 587–5086.

i. *FERC Contact:* Dianne Rodman, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426; telephone (202) 502–6077 or by e-mail at *dianne.rodman@ferc.gov.*

j. Deadline for filing motions to intervene and protests, comments, terms and conditions, recommendations, and prescriptions: 60 days from the issuance of this notice. All reply comments must be filed with the Commission within 105 days from the date of this notice.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Motions to intervene, protests, comments, terms and conditions, recommendations, and prescriptions may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The proposed Greenfield Project would be built at the Greenfields Main Canal's Greenfield drop structure. The applicant proposes to construct: (1) An inflatable weir spanning the width of the canal; (2) an intake structure with trash rack and radial gate or stop-log shut off; (3) a buried, 60-inch-diameter, 530-foot-long steel or polyethylene penstock; (4) a powerhouse containing one Francis or propeller (Reaction) turbine and one generator with a rated output of 600 kilowatts; (5) a tailrace returning flows to the canal; (6) a switchyard; and (7) a 512-foot-long, 12-kilovolt transmission line interconnecting with an existing powerline. Average annual generation would be 1.5 gigawatt hours.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A

notice of intent must be served on the applicant named in this public notice.

Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''COMMENTS'', ''REPLY COMMENTS'', ''RECOMMENDATIONS'', ''TERMS AND CONDITIONS'', or ''PRESCRIPTIONS''; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. License applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–19472 Filed 8–21–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–454–000]

Liberty Gas Storage, LLC; Notice of Application

August 14, 2008.

Take notice that on July 31, 2008, Liberty Gas Storage, LLC (Liberty Gas), 101 Ash Street, San Diego, CA 92101, filed in the above referenced docket an application pursuant to section 7(c) of the Natural Gas Act (NGA), for an order granting a certificate of public convenience to construct new natural gas storage, comprised of three existing salt dome caverns and the development of a new salt dome cavern, pipeline and appurtenant facilities. The new facilities will be located in Cameron and Calcasieu Parishes, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to William Rapp, Liberty Gas Storage, 101 Ash Street, San Diego, CA 92101 or by phone at (619) 699–5050.

Liberty Gas' new storage project has been designed to provide approximately 18.9 billion cubic feet (Bcf) of working gas capacity with a maximum injection rate of up to 600 million cubic feet (Mcf) per day and a maximum withdrawal rate of up to 1.2 Bcf per day. Additionally, Liberty Gas intends to construct 5.1 miles of 36-inch diameter pipeline to deliver the natural gas to Cameron Interstate Pipeline, LLC, as well as one 18,940 horsepower compressor station, a 4.0 mile brine disposal pipeline and water supply facilities necessary to develop the proposed new cavern.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's

environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: September 4, 2008.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–19473 Filed 8–21–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR08–15–002]

Energy Transfer Fuel, LP; Notice of Compliance Filing

August 14, 2008.

Take notice that on August 11, 2008, Energy Transfer Fuel, LP filed a Statement of Operating Conditions pursuant to section 284.123(e) of the Commission's regulations and to comply with the July 11, 2008, order issued in Docket Nos. PR08–15–000 and PR08–15–001.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before the date as indicated.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment date is: 5 p.m. Eastern Time on Friday, August 22, 2008.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–19469 Filed 8–21–08; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8584–8]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 08/11/2008 Through 08/15/2008 Pursuant to 40 CFR 1506.9.

EIS No. 20080314, Draft EIS, NOA, OR, Elliott State Forest Habitat Conservation Plan, Proposed Issuance of an Incidental Take Permit, U.S. Army Corps Section 10 and 404 Permits, Coos and Douglas Counties, OR, *Comment Period Ends:* 11/20/2008, *Contact:* Chuck Wheeler 541–957–3379.

EIS No. 20080315, Second Draft Supplement, BLM, NV, Betze Pit Expansion Project, Development of New Facilities and Expansion of Existing Open-Pit Gold Mining, Eureka and Elko Counties, NV, *Comment Period Ends:* 10/06/2008, *Contact:* Kirk Laird 775–753–0272.

EIS No. 20080316, Final EIS, BLM, UT, Vernal Field Office Resource Management Plan, To Revise and Integrate the Book Cliff and Diamond Mountain Resource Management Plans, and Analyzing the Management of Non-Wilderness Study Area Lands with Wilderness Characteristic, Implementation, Daggett, Duchesne, Uintah, and Grand Counties, UT, *Wait Period Ends:* 09/22/2008, *Contact:* Kelly Buckner 435–781–4400.

EIS No. 20080317, Final EIS, FHW, 00, Interstate 73 North Project, Construct on New Alignment, from I–95 to Future I–74 in NC, Funding, U.S. Army COE Section 404 Permit, Dillon and Malboro Counties, SC, and Richmond and Scotland Counties, NC, *Wait Period Ends:* 09/22/2008, *Contact:* Patrick L. Tyndall 803–765–5460.

EIS No. 20080318, Final EIS, BLM, WY, Pinedale Resource Management Plan, Implementation, of Public Lands Administered, Pinedale Field Office, Sublette and Lincoln Counties, WY, *Wait Period Ends:* 09/22/2008, *Contact:* Ken Peacock 307–775–6113.

EIS No. 20080319, Draft EIS, FAA, AK, Sitka Rocky Gutierrez Airport Master Plan, Improvements to the Runway Safety Area, Taxiway. Seaplane Pullout, Approach Lighting System, and the Seawall, U.S. Army COE Section 10 and 404 Permits, NPDES Permit, AK, *Comment Period Ends:* 10/14/2008, *Contact:* Patricia Sullivan 907–271–5454.

EIS No. 20080320, Draft Supplement, NOA, 00, Amendment 18 to the Fishery Management Plan, Pelagic Fisheries of the Western Pacific Region, Management Modifications for the Hawaii-based Shallow-set Longline Swordfish Fishery, Proposal to Remove Effort Limits, Eliminate the Set Certificate Program and Implement New Sea Turtle Interaction Caps, *Comment Period Ends:* 10/06/2008, *Contact:* William Robinson 808–944–2200.

EIS No. 20080321, Final EIS, FHW, CA, Phase I—CA 11 Corridor Location and Route Adoption and Location Identification of the Otay Mesa East Port of Entry (POE) on Otay Mesa, Presidential Permit for the POE and Acquisition of Right-Of-Way Permit, San Diego County, CA, *Wait Period Ends:* 09/22/2008, *Contact:* Cesar E. Perez 916–498–5065.

EIS No. 20080322, Final EIS, NRC, GA, Vogtle Electric Generating Plant Site, Early Site Permit (ESP), for the Construction and Operation of a new Nuclear Power Generating Facility Application Approval, Burke County, GA NUREG 1872, *Wait Period Ends:*

09/22/2008, *Contact:* Mark D. Notich 301–415–3053.

EIS No. 20080323, Final EIS, CGD, 00, Rulemaking for Dry Cargo Residue (DCR) Discharges in the Great Lakes, To Regulate Nonhazardous and Nontoxic DCR Sweeping from Vessels in the Great Lakes that fall under the Jurisdiction of the United States, *Wait Period Ends:* 09/22/2008, *Contact:* Gregory Kirkbride 202–372–1479.

EIS No. 20080324, Final EIS, BLM, WY, Kemmerer Field Office Planning Area, Resource Management Plan, Implementation, Lincoln, Sweetwater and Uinta Counties, WY, *Wait Period Ends:* 09/22/2008, *Contact:* Michele Easley 307–828–4524.

EIS No. 20080325, Final EIS, NRC, CA, Generic—License Renewal of Nuclear Plants (GEIS) Regarding Shearon Harris Nuclear Power Plant, Unit 1, Plant-Specific Supplement 33 to NUREG–1437, Wake County, NC, *Wait Period Ends:* 09/22/2008, *Contact:* Samuel Hernandez 301–415–4049.

Amended Notices

EIS No. 20080282, Draft EIS, UPS, CA, Aliso Viejo Incoming Mail Facility, Proposed Construction and Operation of a Mail Processing Facility on a 25-Acre Parcel, Aliso Viejo, Orange County, CA, *Comment Period Ends:* 10/23/2008, *Contact:* Emmy Andrews 650–615–7200.

Revision to FR Notice Published 7/25/2008: Extending Comment Period from 9/08/2008 to 10/23/2008.

Dated: August 19, 2008.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E8–19535 Filed 8–21–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8584–9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at 202–564–7146.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 6, 2008 (73 FR 19833).

Draft EISs

EIS No. 20080206, ERP No. D–COE–K39112–CA, Middle Harbor Redevelopment Project, Proposal to Increase Container Terminal Efficiency to Accommodate a Portion of the Predicted Future Containerized Cargo, Section 10 and 404 Permits, Port of Long Beach, Los Angeles County, CA.

Summary: EPA expressed environmental concerns about unavoidable impacts to air quality, environmental justice communities, aquatic and biological resources. EPA recommended commitments to meet air emission reductions, coordination with the environmental justice community to identify additional measures to offset health impacts, avoidance of fill, and development of a port-wide vessel whale strike avoidance program. Rating EC2.

EIS No. 20080230, ERP No. D–COE–K39113–CA, Natomas Levee Improvement Project, Issuing of 408 Permission and 404 Permit, Sacramento Area Flood Control Agency, Sutter and Sacramento, CA.

Summary: EPA expressed environmental concerns about the proposal's compliance with the Clean Water Act Section 404(b)(1) Guidelines and potential impacts to wetlands. EPA also expressed environmental concerns about potential impacts to air quality, as well as the indirect and cumulative impacts of residential development associated with the levee improvement project and the residual flood risk to residential developments in the floodplain. EPA recommended that additional information be provided in the Final EIS regarding compliance with the Section 404(b)(1) Guidelines, floodplain management efforts in the area, and how the project and future development would be consistent with the Natomas Basin Habitat Conservation Plan Rating EC2.

EIS No. 20080241, ERP No. D–USN–D11044–00, Virginia Capes (VACAPES) Range Complex, Proposed action is to Support and Conduct Current and Emerging Training and RDT & E Operations, Chesapeake Bay, DE, MD, VA, and NC.

Summary: EPA expressed environmental concerns about impacts to the Lower Chesapeake Bay, water quality, marine mammals/threatened and endangered species, historic resources, effects from hazardous materials, and cumulative impacts. Additional information was requested to better assess the impacts. Rating EC2.

Final EISs

EIS No. 20080247, ERP No. F–NCP–D61060–DC, Smithsonian Institution National Museum of African American History and Culture, Construction and Operation, Between 14th and 15th Streets NW., and Constitution Avenue, NW., and Madison Drive, NW., Washington, DC.

Summary: EPA's previous issues have been resolved; therefore, EPA does not object to the proposed action.

Dated: August 19, 2008.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E8–19517 Filed 8–21–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8707–9]

Science Advisory Board Staff Office; Notification of a Upcoming Public Teleconference of the Science Advisory Board Ecological Processes and Effects Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office announces a public teleconference of the SAB Ecological Processes and Effects Committee Augmented for the Advisory on EPA's Aquatic Life Water Quality Criteria. The teleconference is being held to discuss the Committee's draft advisory report.

DATES: The public teleconference will be held on September 16, 2008 from 1 p.m. to 4 p.m. (Eastern Daylight Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain the call-in number and access code to participate in the teleconference may contact Dr. Thomas Armitage, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone/voice mail: (202) 343–9995; fax (202) 233–0643; or via e-mail at: *armitage.thomas@epa.gov.* General information about the EPA SAB, as well as any updates concerning the teleconference announced in this notice, may be found on the SAB Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the SAB Ecological Processes

and Effects Committee Augmented for the Advisory on EPA's Aquatic Life Water Quality Criteria will hold a public teleconference to discuss their draft report. The SAB was established by 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: EPA's Office of Water has requested that the SAB provide advice on an EPA white paper describing technical challenges and recommendations concerning derivation of aquatic life water quality criteria for contaminants of emerging concern. The SAB Ecological Processes and Effects Committee, augmented with additional experts, held a teleconference on June 23, 2008 and a meeting on June 30–July 1, 2008 to review the EPA white paper. A **Federal Register** notice dated June 4, 2008 (73 FR 31864–31865) announced these meetings and provided background information on this advisory activity. Information on the process of augmenting the expertise on the SAB Ecological Processes and Effects Committee was provided in a **Federal Register** notice dated May 2, 2008 (73 FR 24285–24286). The purpose of this upcoming teleconference is for the Committee to discuss its draft advisory report. Additional information about this advisory activity can be found on the SAB Web site at *http://www.epa.gov/sab.* A teleconference agenda and the draft SAB advisory report will be posted at the above noted SAB Web site prior to the teleconference.

Availability of Meeting Materials: The teleconference agenda and other materials including the SAB Committee's draft report will be available on the SAB Web site at *http://www.epa.gov/sab* in advance of the teleconference.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the SAB Panel to consider during the advisory process.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public teleconference will be limited to three minutes per speaker, with no more than a total of 30 minutes for all speakers. Interested parties should contact Dr. Armitage, DFO, in writing (preferably via e-mail) at the contact information noted above, by September 9, 2008 to be placed on the list of public speakers for the teleconference.

Written Statements: Written statements should be received in the SAB Staff Office by September 9, 2008 so that the information may be made available to the SAB Panel members for their consideration. Written statements should be supplied to the DFO in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format).

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Armitage at the phone number or e-mail address noted above, preferably at least ten days prior to the meeting to give EPA as much time as possible to process your request.

Dated: August 18, 2008.

Anthony F. Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E8–19515 Filed 8–21–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket # EPA–RO4–SFUND–2008–0608, FRL–8707–8]

J & W Pallet and Drum Company Superfund Site, Atlanta, Fulton County, GA; Notice of Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of settlement.

SUMMARY: Under Section 122(h)(1) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency has entered into a settlement for reimbursement of past response costs concerning the J & W Pallet and Drum company Superfund Site located in Atlanta, Fulton County, Georgia for publication.

DATES: The Agency will consider public comments on the settlement until September 22, 2008. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

ADDRESSES: Copies of the settlement are available from Ms. Paula V. Painter. Submit your comments, identified by Docket ID No. EPA–RO4–SFUND–2008–0608 or Site name J & W Pallet and Drum Company Superfund Site by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- E-mail: *Painter.Paula@epa.gov.*
- Fax: 404/562–8842/Attn Paula V. Painter.
- *Mail:* Ms. Paula V. Painter, U.S. EPA Region 4, SD–SEIMB, 61 Forsyth Street, SW., Atlanta, Georgia 30303. ''In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.''

Instructions: Direct your comments to Docket ID No. EPA–R04–SFUND–2008–0608. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is

not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the U.S. EPA Region 4 office located at 61 Forsyth Street, SW., Atlanta, Georgia 30303. Regional office is open from 7 a.m. until 6:30 p.m. Monday through Friday, excluding legal holidays.

Written comments may be submitted to Ms. Painter within 30 calendar days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: Paula V. Painter at 404/562–8887.

Dated: August 1, 2008.

Anita L. Davis,

Chief, Superfund Enforcement & Information Management Branch, Superfund Division.

[FR Doc. E8–19516 Filed 8–21–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[CG Docket No. 03–123; DA 07–3998]

Notice of Certification of Hawk Relay, LLC as a Provider of Internet Protocol Relay (IP Relay) and Video Relay Service (VRS) Eligible for Compensation From the Interstate Telecommunications Relay Service (TRS) Fund

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission's Consumer and Governmental Affairs Bureau (Bureau) grants the application of Hawk Relay, LLC (Hawk Relay) for certification as a provider of IP Relay and VRS eligible for compensation from the Interstate TRS Fund (Fund). The Commission concludes that Hawk Relay has demonstrated adequately that its provision of IP Relay and VRS will meet or exceed all operational, technical, and functional TRS standards set forth in the Commission's rules; that it makes available adequate procedures and remedies for ensuring compliance with applicable Commission rules; and that to the extent Hawk Relay's service differs from the mandatory minimum standards, the service does not violate the rules.

DATES: Effective September 21, 2007.

FOR FURTHER INFORMATION CONTACT: Gregory Hlibok, Consumer and Governmental Affairs Bureau, Disability Rights Office at (800) 311–4381 (Voice), (202) 418–0431 (TTY), or e-mail at *Gregory.Hlibok@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Bureau's document DA 07–3998, released September 21, 2007, addressing Hawk Relay's application for certification as a provider of IP Relay and VRS eligible for compensation from the Fund. *See Notice of Certification of Hawk Relay, LLC as a Provider of Internet Protocol Relay (IP Relay) and Video Relay Service (VRS) Eligible for Compensation from the Interstate Telecommunications Relay Service (TRS) Fund,* CG Docket No. 03–123, Public Notice, 22 FCC Rcd 17020 (CGB 2007). The full texts of document DA 07–3998 and Hawk Relay's application are available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. These documents also may be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554; the contractor's Web site, *http://www.bcpiweb.com;* or by calling (800) 378–3160. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY). Document DA 07–3998 also can be downloaded in Word or Portable Document Format (PDF) at: *http://www.fcc.gov/cgb/drotrs.html.* In addition, Hawk Relay's application also may be found by searching in the Commission's Electronic Comment Filing System (ECFS) at *http://www.fcc.gov/cgb/ecfs* (insert 03–123 into the Proceeding block).

Synopsis

On January 3, 2007, Hawk Relay filed an application for certification as a provider of IP Relay and VRS eligible for compensation from the Fund pursuant to the Commission's IP Relay and VRS provider certification rules, adopted in *Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket No. 03–123, Report and Order and Order on Reconsideration, 20 FCC Rcd 20577 (2005); published at 70 FR 76208, December 23, 2005. On July 9, 2007, Hawk Relay resubmitted its application. Hawk Relay's revised application of July 9, 2007 is granted.

The Bureau has reviewed Hawk Relay's revised application pursuant to the provider certification rules. The Bureau concludes that Hawk Relay has adequately demonstrated that its provision of IP Relay and VRS services will meet or exceed all operational, technical, and functional TRS standards set forth in 47 CFR 64.604; that it makes available adequate procedures and remedies for ensuring compliance with applicable Commission rules; and that to the extent Hawk Relay's service differs from the mandatory minimum standards, the service does not violate the rules.

Hawk Relay's application is granted subject to compliance with applicable Commission orders, including the declaratory ruling requiring the interoperability of VRS equipment and service. *See Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket No. 03–123, Declaratory Ruling and Further Notice of Proposed Rulemaking, 21 FCC Rcd 5442 (2006); published at 71 FR 30818, May 31, 2006 and 71 FR 30848, May 31, 2006. Further, Hawk Relay must file an annual report with the Commission demonstrating that Hawk Relay is in compliance with 47 CFR 64.604. The first such report shall be due one year after September 21, 2007, and subsequent reports shall be due each year thereafter. This certification shall remain in effect for a period of five years from September 21, 2007. Within ninety days prior to the expiration of this certification, Hawk Relay may apply for renewal of its IP Relay and VRS provider certification by filing documentation in accordance with the Commission's rules.

Federal Communications Commission.

Nicole McGinnis,

Deputy Chief, Consumer and Governmental Affairs Bureau.

[FR Doc. E8–19546 Filed 8–21–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CG Docket No. 03–123; DA 07–3996]

Notice of Certification of CSDVRS, LLC as a Provider of Video Relay Service (VRS) Eligible for Compensation From the Interstate Telecommunications Relay Service (TRS) Fund

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission's Consumer and Governmental Affairs Bureau (Bureau) grants the application of CSDVRS, LLC (CSDVRS) for certification as a VRS provider eligible for compensation from the Interstate TRS Fund (Fund). The Commission concludes that CSDVRS has demonstrated sufficiently that its provision of VRS will meet or exceed all operational, technical, and functional TRS standards set forth in the Commission's rules; that it makes available adequate procedures and remedies for ensuring compliance with applicable Commission rules; and that to the extent CSDVRS's service differs from the mandatory minimum standards, the service does not violate the rules.

DATES: Effective September 21, 2007.

FOR FURTHER INFORMATION CONTACT: Gregory Hlibok, Consumer and Governmental Affairs Bureau, Disability Rights Office at (800) 311–4381 (Voice), (202) 418–0431 (TTY), or e-mail at *Gregory.Hlibok@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Bureau's document DA 07–3996, released September 21, 2007, addressing CSDVRS's application for certification as a VRS provider eligible for compensation from the Fund. *See Notice of Certification of CSDVRS, LLC as a Provider of Video Relay Service (VRS) Eligible for Compensation from the Interstate Telecommunications Relay Service (TRS) Fund,* CG Docket No. 03–123, Public Notice, 22 FCC Rcd 17014 (CGB 2007). The full texts of document DA 07–3996 and CSDVRS's application are available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. These documents also may be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554; the contractor's Web site, *http://www.bcpiweb.com;* or by calling (800) 378–3160. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY). Document DA 07–3996 also can be downloaded in Word or Portable Document Format (PDF) at: *http://www.fcc.gov/cgb/dro/trs.html.* In addition, CSDVRS's application also may be found by searching in the Commission's Electronic Comment Filing System (ECFS) at *http://www.fcc.gov/cgb/ecfs* (insert 03–123 into the Proceeding block).

Synopsis

On July 16, 2007, CSDVRS filed an application for certification as a provider of VRS eligible for compensation from the Fund pursuant to the Commission's provider certification rules, adopted in *Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket No. 03–123, Report and Order and Order on Reconsideration, 20 FCC Rcd 20577 (2005); published at 70 FR 76208, December 23, 2005. CSDVRS's application is granted. The Bureau has reviewed CSDVRS's application pursuant to the provider certification rules. The Bureau concludes that CSDVRS has sufficiently demonstrated that its provision of VRS service will meet or exceed all operational, technical, and functional TRS standards set forth in 47 CFR 64.604; that it makes available adequate procedures and remedies for ensuring compliance with applicable Commission rules; and that to the extent CSDVRS's service differs from the mandatory minimum standards, the service does not violate the rules.

CSDVRS's application is granted subject to compliance with applicable Commission orders, including the declaratory ruling requiring the interoperability of VRS equipment and service. *See Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket No. 03–123, Declaratory Ruling and Further Notice of Proposed Rulemaking, 21 FCC Rcd 5442 (2006); published at 71 FR 30818, May 31, 2006 and 71 FR 30848, May 31, 2006. Further, CSDVRS must file an annual report with the Commission demonstrating that CSDVRS is in compliance with 47 CFR 64.604. The first such report shall be due one year after September 21, 2007, and subsequent reports shall be due each year thereafter. This certification shall remain in effect for a period of five years from September 21, 2007. Within ninety days prior to the expiration of this certification, CSDVRS may apply for renewal of its VRS service certification by filing documentation in accordance with the Commission's rules.

Federal Communications Commission.

Nicole McGinnis,

Deputy Chief, Consumer and Governmental Affairs Bureau.

[FR Doc. E8–19547 Filed 8–21–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of information collection to be submitted to OMB for review and approval under the Paperwork Reduction Act of 1995.

SUMMARY: In accordance with requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the FDIC hereby gives notice that it is submitting to the Office of Management and Budget (OMB) a request for OMB review and approval of the new information collection described below. The collection is related to a mandate under section 7 of the Federal Deposit Insurance Reform Conforming Amendments Act of 2005 (''Reform Act'') (Pub. L. 109–173), which calls for the FDIC to conduct ongoing surveys ''on efforts by insured depository institutions to bring those individuals and families who have rarely, if ever, held a checking account, a savings account or other type of transaction or check cashing account at an insured depository institution (hereafter in this section referred to as the 'unbanked') into the conventional finance system.'' Section 7 further instructs the FDIC to consider several factors in its conduct of the surveys, including: (1) ''What cultural, language and identification issues as well as transaction costs appear to most prevent 'unbanked' individuals from establishing conventional accounts''; and (2) ''What is a fair estimate of the size and worth of the 'unbanked' market in the United States.''

To satisfy the Congressional mandate, the FDIC intends to conduct two complementary surveys. One is a survey of FDIC-insured depository institutions on their efforts to serve underbanked, as well as unbanked, populations (underbanked populations include individuals who have an account with an insured depository but also rely on non-bank alternative financial service providers for transaction services or high-cost credit products). The FDIC has already obtained OMB approval for this

survey and the survey effort is currently in process. The other is a survey of U.S. households to estimate the size and worth of the unbanked and underbanked markets and to identify the factors that inhibit their participation in the mainstream banking system. The household survey would be conducted for the FDIC by the U.S. Bureau of the Census, as a supplement to its monthly Current Population Survey (CPS) in January 2009. This notice addresses the household survey.

DATES: Comments must be submitted on or before September 22, 2008.

ADDRESSES: Interested parties are invited to submit written comments on the collection of information entitled: National Unbanked and Underbanked Household Survey. Comments should refer to the name of the collection and may be submitted by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federalnotices.html.*
- *E-mail: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Leneta G. Gregorie (202.898.3719), Counsel, Federal Deposit Insurance Corporation, Room F–1064, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 550 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

A copy of the comments should also be submitted to the OMB Desk Officer for the FDIC, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Interested members of the public may obtain a copy of the survey and related instructions by clicking on the link for the *National Unbanked and Underbanked Household Survey* on the following Web page: *http://www.fdic.gov/regulations/laws/federal/index.html.* Interested members of the public may also obtain additional information about the collection, including a paper copy of the proposed collection and related instructions, without charge, by contacting Leneta Gregorie at the address identified above, or by calling (202) 898–3719.

SUPPLEMENTARY INFORMATION:

Proposal to seek OMB approval for the following new collection of information:

Title: National Unbanked and Underbanked Household Survey.

OMB Number: New collection.

Frequency of Response: Once.

Affected Public: U.S. Households.

Estimated Number of Respondents: 54,000.

Average time per response: 10 minutes (0.166 hours) per respondent.

Estimated Total Annual Burden: 0.166 hours × 54,000 respondents = 8,964 hours.

General Description of Collection: This collection is related to a mandate under section 7 of the Federal Deposit Insurance Reform Conforming Amendments Act of 2005 (''Reform Act'') (Pub. L. 109–173), which calls for the FDIC to conduct ongoing surveys ''on efforts by insured depository institutions to bring those individuals and families who have rarely, if ever, held a checking account, a savings account or other type of transaction or check cashing account at an insured depository institution (hereafter in this section referred to as the 'unbanked') into the conventional finance system.'' The Congressional mandate further requires the FDIC to conduct ongoing surveys to, among other things, estimate the size and worth of the unbanked market in the United States and to identify the cultural, language and identification issues as well as transaction costs that appear to most prevent unbanked individuals from establishing accounts with insured depository institutions.

To satisfy the Congressional mandate, the FDIC has proposed conducting two complementary surveys related to unbanked and underbanked consumers (underbanked consumers include individuals who have an account with an insured depository institution, but also rely on non-bank alternative financial service providers for transaction services or high-cost credit products).

The first survey effort, which has already obtained OMB approval and is currently underway, is a survey of FDIC-insured depository institutions on their efforts to serve unbanked and underbanked consumers. The second survey effort, which is the subject of this notice, would be a national survey of U.S. households to estimate the size and worth of the unbanked and underbanked markets and to identify the barriers households perceive when deciding how and where to conduct financial transactions.

To obtain the information required by the Reform Act related to unbanked and underbanked households, for this survey effort the FDIC proposes to partner with the U.S. Census Bureau to conduct a survey of U.S. households as a supplement to Census' CPS in January 2009. The supplement would be administered to households that participate in the CPS and would be 10 minutes in length, on average. Based on their responses to the survey questions, respondents will be classified as unbanked or underbanked, allowing estimation of the size of those populations, and information on their demographic characteristics will be derived from their responses to demographic questions in the CPS.

The FDIC supplement to the Census survey is designed to yield significant new data on the numbers and demographic characteristics of unbanked and underbanked households, as well as the barriers they perceive when deciding how and where to conduct financial transactions. Currently, there is a lack of basic data on the number of unbanked and underbanked households in the U.S. and on the factors that may promote or hinder access to the mainstream financial system. This will be the first survey of its kind on this topic to be conducted at the national level and results will also be reportable at the state level. The results will help policymakers and the industry better understand the extent to which U.S. households are financially underserved, the reasons why U.S. households may be financially underserved, and the opportunities that exist to better serve them.

Comment Discussion: On May 19, 2008 (73 FR 28824), the FDIC issued a request for comment on the proposed National Survey of Unbanked and Underbanked Households. One comment was received from a banking trade organization. The commenter expressed general support for the survey, noting that the banking industry is actively searching for ways to expand the universe of bank customers by identifying ways to transition unbanked consumers into users of mainstream products and services. The commenter indicated that the survey data would enhance these private initiatives to develop financial services for unbanked and underbanked consumers. The commenter did, however, express concern that certain questions may be phrased in such a way as to unintentionally steer respondents to certain answers which are critical of banks and that several questions offer the failure of banks to provide check cashing services, a service banks usually provide to their account holders, as a possible reason for not having or closing a bank account. To mitigate the possibility of unintentional steering, the commenter suggested that the FDIC consult with experts in the field of

polling to determine whether there are more neutral and reliable ways to elicit the information sought. The commenter further suggested that the FDIC eliminate failure to provide check cashing services as a possible answer to questions probing the reasons a respondent does not have or has closed an account.

The commenter also suggested that the FDIC expand the survey, to elicit more detailed information in a number of areas, including the attitudes of the unbanked toward financial education opportunities; the reasons some consumers prefer to operate on a cash basis; what consumers like and dislike about payroll cards and other pre-paid products and the extent to which users of such products tend to be interested in opening checking or savings accounts; and the extent to which price and other factors affect the choices made by unbanked consumers when shopping for financial products and services. Finally, the commenter noted that the survey does not include questions of a demographic nature such as the respondent's age, education, income, line of work, ethnicity, or how long he or she has resided in the country. The commenter, therefore, requested that the FDIC incorporate demographic questions into the survey or clarify that such questions will be included as part of the regularly scheduled questions asked by census takers.

In its development of the survey questions for the National Survey of Unbanked and Underbanked Households, the FDIC attempted to balance its statutory mandate to identify the factors that appear to prevent unbanked individuals from establishing accounts with insured depository institutions and the demographic characteristics of the unbanked population against the need to minimize burden on respondents. To achieve this balance and to ensure that the questions were structured in a way to minimize bias, the FDIC consulted with a nationally recognized polling firm with expert credentials in qualitative and quantitative research and analysis. The FDIC also worked closely with a cognitive testing expert on the faculty of the University of Connecticut and with staff of the Census Bureau's Demographic Surveys Division and the Labor Department's Bureau of Labor Statistics. After two rounds of cognitive testing with corresponding adjustments to survey questions, the FDIC is confident that the survey questions are structured in a way that minimizes possible skewing of survey results.

With respect to suggested deletion of failure to provide check cashing services as a potential response to questions seeking information on the reasons for not having or closing an account, the FDIC is aware that such services are usually extended to bank customers. However, provision of such services to account holders is not always the case and, in many instances, may be restricted by several factors such as account standing and the institution on which the check is drawn. Therefore, the FDIC believes that failure to provide check cashing services is a valid response option for questions seeking to determine the reasons for not having or closing an account.

Regarding the suggestion that the FDIC expand the survey to elicit more detailed information in a variety of areas, the FDIC agrees that the utility of the survey would be enhanced by the addition of questions that would provide more depth on factors underlying consumer choices and preferences with respect to financial products and services. However, the FDIC is constrained by Census Bureau limits on the length of the survey. Perhaps these issues can be explored in future survey efforts.

On the demographic issues raised by the commenter, the FDIC has clarified that demographic information about respondents is collected by the Current Population Survey, eliminating the need for such questions to be included in the supplemental survey.

Request for Comment

Comments are invited on: (a) Whether these collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimate of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collections on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 19th day of August, 2008.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. E8–19478 Filed 8–21–08; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

Correction

In notice document E8–17716 beginning on page 45222 in the issue of Monday, August 4, 2008, make the following correction:

On page 45223, in the first column, under **DATES:**, in the second line, ''September 30, 2008'' should read ''October 3, 2008''.

[FR Doc. Z8–17716 Filed 8–21–08; 8:45 am]

BILLING CODE 1505–01–D

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 9, 2008.

A. Federal Reserve Bank of Kansas City (Todd Offenbacker, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. Steven J. Buchanan, Omaha, Nebraska, as a member of Wilber Co. Voting Trust; to retain control of Wilber Co., both of Wilber, Nebraska, parent of First State Bank, Lincoln, Nebraska.

Board of Governors of the Federal Reserve System, August 19, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–19529 Filed 8–21–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval,

pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 18, 2008.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Bank of America Corporation, and NB Holdings Corporation, both of Charlotte, North Carolina; to acquire 100 percent of the voting securities of Bank of America Illinois, National Association, Chicago, Illinois (in organization), and Bank of America Michigan, National Association, Troy, Michigan (in organization).

B. Federal Reserve Bank of Atlanta (Steve Foley, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Piedmont Bancorp, Inc., Norcross, Georgia; to become a bank holding company by acquiring 100 percent of the outstanding shares of First Choice Community Bank 1874, Newnan, Georgia.

Board of Governors of the Federal Reserve System, August 19, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–19528 Filed 8–21–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 9, 2008.

A. Federal Reserve Bank of Atlanta (Steve Foley, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Banco de Sabadell, S.A., Sabadell, Spain, and its subsidiary, TransAtlantic Holding Corp., Miami, Florida; to engage de novo in making, acquiring, brokering or servicing loans or other extensions of credit through a newly-formed subsidiary, Interstate Property Holdings, LLC, Miami, Florida, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, August 19, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–19526 Filed 8–21–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New; 30-Day Notice]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–6974..

Proposed Project: Trends in U.S. Public Awareness of Racial and Ethnic Health Disparities (1999–2008)—New-Office of Minority Health (OMH).

Abstract: The proposed survey seeks to collect data for one of OMH's annual performance measures, approved by OMB in February 2007, following Office of Management and Budget (OMB)'s examination of OMH using the Program Assessment Rating Tool (PART). This measure is to ''increase awareness of

racial/ethnic health status and health care disparities in the general population.'' Findings from this data collection will enable OMH to track progress on this measure over time as mandated by OMB PART requirements.

The lack of general awareness and understanding about the nature and extent of racial and ethnic health disparities in the U.S. and the impact that such disparities are having on the overall health of the Nation have been cited as a major barrier to the provision of programmatic, budgetary, and policy attention to these issues. Therefore, one of the long-term, annual measures agreed upon was to ''increase awareness of racial/ethnic health status and health care disparities in the general population.''

Additionally, OMH can use the findings about progress made in raising awareness to identify collaborative partners in the federal government, at the state and local levels, among businesses and non-profits, and among the faith community, in order to reach a wider audience. These results can be used by program decision-makers and policy-makers, within and outside of HHS, who are interested in capturing progress made in the last eight years after exposing the U.S. population to information which confirms the existence, and societal effects, of racial and ethnic health disparities.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
General Population	4,100	1	14/60	957
Physician	360	1	14/60	84
Total				1,041

Terry Nicolosi,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E8–19460 Filed 8–21–08; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0290; 30-day notice]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–6974.

Proposed Project: Evaluating the Title XX Adolescent Family Life (AFL) Program: Care Demonstration Projects—OMB No. 0990–0290—Revision—Office of Adolescent Pregnancy Programs (OAPP).

Abstract: The Office of Adolescent Pregnancy Programs (OAPP) is requesting approval from the Office of Management and Budget (OMB) to revise a currently approved collection of information conducting a cross-site evaluation of the Adolescent Family Life (AFL) care demonstration program utilizing revised core evaluation instruments. ''Evaluating the Title XX Adolescent Family Life (AFL) Program: Care Demonstration Projects'' is authorized by Title XX of the Public Health Service Act. The program is requesting 3 year approval. Respondents will be pre-adolescents and adolescents aged 9–19 participating in the care demonstration projects and will complete pre-intervention surveys and post-intervention surveys. The affected public will be individuals in the demonstration projects and comparison participants.

ESTIMATED ANNUALIZED BURDEN TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Baseline Care survey for pregnant adolescents	3,333	1	23/60	1,278
Baseline Care survey for parenting adolescents	1,000	1	23/60	383
Follow-up survey (at birth)	3,333	1	23/60	1,278
Follow-up Care survey (6 months after birth)	4,333		23/60	1,661
Follow-up Care survey (12 months after birth)	4,333	1	23/60	1,661
Total				6,261

Terry Nicolosi,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E8–19536 Filed 8–21–08; 8:45 am]

BILLING CODE 4150–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0291; 30-day notice]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–6974.

Proposed Project: Evaluating the Title XX Adolescent Family Life (AFL) Program: Prevention Demonstration Projects—OMB No. 0990–0291–Revision—Office of Adolescent Pregnancy Programs (OAPP).

Abstract: The Office of Adolescent Pregnancy Programs (OAPP) is requesting approval by the Office of Management and Budget (OMB) to revise a previously approved collection of information conducting a cross-site evaluation of the Adolescent Family Life (AFL) prevention demonstration program utilizing revised core evaluation instruments. ''Evaluating the Title XX Adolescent Family Life (AFL) Program: Prevention Demonstration Projects'' is authorized by Title XX of the Public Health Service Act. The project is requesting a 3 year approval. Respondents will be adolescents and pre-adolescents aged 9–19 participating in the prevention demonstration projects and will complete pre-intervention surveys and post-intervention surveys. The affected public will be individuals in the demonstration projects and comparison participants.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Baseline survey	13,333	1	22/60	4889
Year 1 Follow-up survey	13,333	1	22/60	4889
Year 2 Follow-up survey	13,333	1	22/60	4889
Total				14,667

Terry Nicolosi,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E8–19537 Filed 8–21–08; 8:45 am]

BILLING CODE 4150–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities.'' This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register**.

The Secretary of the Treasury has certified a rate of 11⅛% for the quarter ended June 30, 2008. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: August 13, 2008.

Molly P. Dawson,

Director, Office of Financial Policy and Reporting.

[FR Doc. E8–19502 Filed 8–21–08; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a public meeting. The meeting is open to the public.

DATES: The NBSB will hold a public meeting on September 23, 2008 from 1 p.m. to 4 p.m. EST.

ADDRESSES: The Sheraton National Hotel, 900 S. Orme Street, Arlington, VA 22204. Phone: 703–521–1900.

FOR FURTHER INFORMATION CONTACT: CAPT Leigh A. Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense

Science Board, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, 200 Independence Ave, SW., Room 638G, Washington, DC 20201; 202–205–3815; fax: 202–205–0613; e-mail address: *leigh.sawyer@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d–7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary on other matters related to public health emergency preparedness and response.

Background: The National Biodefense Science Board (NBSB) has been asked to provide feedback to the Department of Health and Human Services on the review of the National Disaster Medical System (NDMS) and national medical surge capacity as required by the Pandemic and All-Hazards Preparedness Act of 2006 and as specified by Paragraph 28 of Homeland Security Presidential Directive 21. To accomplish this task, the request for review was forward to the Disaster Medicine Working Group of the NBSB. The Disaster Medicine Working Group convened a NDMS Assessment Panel to consider these issues. The NDMS Assessment Panel is comprised of several NBSB members and includes a wide range of government, public, and private sector subject matter experts on the NDMS and surge capacity.

The purpose of the September 23, 2008 meeting is for the NBSB to consider the final report of the NDMS Assessment Panel and to provide recommendations to the Secretary of the U.S. Department of Health and Human Services. The public meeting will include a report from the NDMS Assessment Panel.

Availability of Materials: The draft agenda and other materials will be posted on the NBSB Web site at *http://www.hhs.gov/aspr/omsph/nbsb/index.html* prior to the meeting.

Procedures for Providing Public Input: Public participation in NBSB meetings is encouraged. Interested members of the public may attend the meeting in person or participate by public teleconference. Any member of the public wishing to obtain information regarding participation by teleconference should contact CAPT Leigh A. Sawyer. Members of the public may submit relevant written or oral information for the NBSB to consider.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public NBSB teleconference will be limited to three minutes per speaker, with no more than a total of one half hour for all speakers. To be placed on the public speaker list, interested parties should contact CAPT Leigh A. Sawyer, in writing (preferably via e-mail), by September 12, 2008.

Written Statements: In general, individuals or groups may file written comments with the committee. All written comments must be received prior to September 12, 2008 and should be sent by e-mail with ''NBSB Public Comment'' as the subject line or by regular mail to the Contact person listed above. Individuals needing special assistance should notify the designated contact person by September 12, 2008.

Dated: August 8, 2008.

RADM William C. Vanderwagen,

Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services.

[FR Doc. E8–19505 Filed 8–21–08; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Planning Ideas for Development of an AHRQ InnovationsResearch Portfolio

Correction

In notice document E8–18671 appearing on page 47952 in the issue of Friday, August 15, 2008, make the following correction:

On page 47952, in the first column, under **FOR FURTHER INFORMATION CONTACT:**, in the second line, ''*francis.chesley@ahrg.hhs.gov*'' should read ''*francis.chesley@ahrq.hhs.gov*''.

[FR Doc. Z8–18671 Filed 8–21–08; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–381, CMS–1893 and 1856, CMS–10249, CMS–10264, CMS–10266, and CMS–855S]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Identification of Extension Units of Outpatient Physical Therapy (OPT)/ Outpatient Speech Pathology (OSP) Providers;

Use: Medicare requires OPT/OSP providers to be surveyed to determine compliance with Federal regulations. All locations where OPT/OSP providers furnish services must meet these requirements. The CMS–381 is the form used to identify all the OPT/OSP locations.

Form Number: CMS–381 (OMB# 0938–0273);

Frequency: Yearly;

Affected Public: State, Local, or Tribal Governments;

Number of Respondents: 495;

Total Annual Responses: 495;

Total Annual Hours: 866.

2. *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Outpatient Physical Therapy Speech Pathology Survey Report and

Supporting Regulations in 42 CFR 485.701–485.729.

Use: The Medicare program requires OPT providers to meet certain health and safety requirements. The request for certification form is used by State agency surveyors to determine if minimum Medicare eligibility requirements are met. The survey report form records the results of the on-site survey.

Form Number: CMS–1856 and 1893 (OMB# 0938–0065);

Frequency: Yearly and occasionally;

Affected Public: State, Local, or Tribal Governments;

Number of Respondents: 495;

Total Annual Responses: 495;

Total Annual Hours: 866.

3. *Type of Information Collection Request:* New Collection;

Title of Information Collection: Administrative Requirements for Section 6071 of the Deficit Reduction Act of 2005 (DRA);

Use: CMS will use an Operational Protocol Instruction Guide and template for the development of Operational Protocols for the States selected to participate in the Money Follows the Person (MFP) Rebalancing Demonstration. The guide will provide instruction on the required elements of the State's Operational Protocol, which must be submitted and approved before a State may enroll individuals in the State's demonstration program or begin to claim service dollars. Section 6071(c)(9) of the DRA requires the States to provide information and assurances that total expenditures under the State Medicaid program for home and community-based long-term care services will not be less for any fiscal year during the MFP demonstration project than for the greater of such expenditures for fiscal year 2005 or any succeeding fiscal year before the first of the year of the MFP demonstration project. Accordingly, States are required to submit Maintenance of Effort (MOE) forms and MFP Budget forms on an annual basis. Additionally, in order to receive enhanced FMAP, States are required to submit the MFP Demonstration Financial Forms on a quarterly basis. Section 6071(g) of the DRA requires a national evaluation of the MFP demonstration project and a final report to the President and Congress. For the national evaluation, States will be required to submit semi-annual reports that describe their progress in implementing their MFP programs and rebalancing their long-term care systems. In addition, States will be required to submit on a quarterly basis an MFP Finders File, which will include eligibility records for all MFP participants, and an MFP Services File, which will include records for each service funded with MFP grant funds. (NOTE: This collection package has been revised since the 60-day **Federal Register** notice published on August 31, 2007. The 30-day collection package includes two additional instruments: (1) MFP Quality of Life (QOL) Survey; and, (2) MFP Semi-annual Progress Report. The MFP QOL Survey is a collection of qualitative data from MFP participants, and the MFP Semi-annual Progress Report is a mechanism for CMS Project Officers to monitor MFP grantees.)

Form Number: CMS–10249 (OMB#: 0938–NEW);

Frequency: Reporting—Yearly, Quarterly, Semi-annually and Once;

Affected Public: States, Local or Tribal Governments;

Number of Respondents: 31;

Total Annual Responses: 360;

Total Annual Hours: 9,360.

4. *Type of Information Collection Request:* New collection;

Title of Information Collection: Medicare Registration Summary and Medication History Personal Health Record Evaluation;

Use: In 2006, the American Health Information Community (AHIC) Consumer Empowerment Workgroup (CEWG) made a recommendation to CMS to pilot programs that measure and demonstrate the value of Personal Health Records (PHRs) for patients with chronic diseases and their clinicians. For this information collection, CMS has proposed to evaluate the uptake, use, and perceived value of a Registration Summary and Medication History PHR tool for Medicare Managed Care and/or Part D Drug Plan Beneficiaries. Seven commercial health plans volunteered to integrate the PHR pilot tool within their existing PHRs, and these plans are offering the tool to member beneficiaries at no cost. CMS will examine how the PHRs were used by the beneficiaries, caregivers and providers and if they were perceived to improve the quality of the beneficiary/provider communication; timeliness of preventive screenings; and ease of use or value of information to individuals with chronic conditions.

Form Number: CMS–10264 (OMB# 0938–New);

Frequency: Once;

Affected Public: Individuals or households, Private Sector;

Number of Respondents: 2,167;

Total Annual Responses: 2,167;

Total Annual Hours: 1083.5.

5. *Type of Information Collection Request:* New collection;

Title of Information Collection: Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplants and Supporting Regulations in 42 CFR 482.74, 482.94, 482.100, 482.102, 488.61;

Use: The Conditions of Participation and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a transplant center qualifies for approval or re-approval under Medicare. CMS and the healthcare industry believe that the availability to the facility of the type of records and general content of records is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability.

Form Number: CMS–10266 (OMB# 0938–New);

Frequency: Yearly;

Affected Public: Business or other for-profits and not-for-profit institutions;

Number of Respondents: 514;

Total Annual Responses: 3,270;

Total Annual Hours: 9,334.

6. *Type of Information Collection Request:* New collection;

Title of Information Collection: Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers and Supporting Regulations in 42 CFR 424.57 and 424.58;

Use: CMS is revising the CMS–855 Medicare Enrollment Applications Package (OMB No. 0938–0685) to remove the CMS–855S application from its collection. CMS has found that the regulations governing the standards required of suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) are revised and increased more frequently than the other provider types reimbursed by Medicare. Consequently, CMS must revise the CMS 855S application for DMEPOS suppliers more often than the CMS 855A, CMS 855B, CMS 855I and CMS 855R enrollment applications. The ability to revise the CMS 855S separately from the other CMS 855 enrollment applications will lessen the burden on both CMS and the public as only one subset of suppliers will be affected by CMS 855S revisions. CMS intends to maintain the continuity of the CMS 855 enrollment applications by using the same formats and lay-out of the current CMS 855 enrollment applications, regardless of the separation of the CMS 855S from the collective enrollment application package. The primary function of the CMS 855S DMEPOS supplier enrollment application is to gather

information from a supplier that tells us who it is, whether it meets certain qualifications to be a health care supplier, where it renders its services or supplies, the identity of the owners of the enrolling entity, and information necessary to establish the correct claims payment.

Form Number: CMS–855S (OMB# 0938–New);

Frequency: Yearly;

Affected Public: Business or other for-profits and not-for-profit institutions;

Number of Respondents: 126,134;

Total Annual Responses: 126,134;

Total Annual Hours: 149,234.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on September 22, 2008.

OMB Human Resources and Housing Branch, *Attention:* OMB Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, *Fax Number:* (202) 395–6974.

Dated: August 14, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–19393 Filed 8–21–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–179]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Transmittal and Notice of Approval of State Plan Material and Medicaid State Plan—Base Plan, Attachments and Supplemental Pages and Supporting Regulations in 42 CFR 430.10–430.20 and 440.167; *Use:* The Medicaid State base plan pages and attachments are documents utilized by State and territorial agencies which have the responsibility for administering the Medicaid program. The Medicaid State plan is comprised of ''pages'' and organized by subject matter which includes Medicaid eligibility services, payment for services, and general, financial and personnel administration. When States seek to change selected pages of their State plans, the page(s) are transmitted to CMS for review and approval by the CMS Central and Regional Offices prior to amending its State plan. *Form Number:* CMS–179 (OMB# 0938–0193); *Frequency:* Once and as needed; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 4,681; *Total Annual Hours:* 9,271.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by October 21, 2008:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 14, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–19395 Filed 8–21–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1417–NC]

Medicare and Medicaid Programs; Announcement of Applications From Hospitals Requesting Waiver for Organ Procurement Service Area

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

ACTION: Notice with comment period.

SUMMARY: This notice announces three hospitals' requests for a waiver from entering into an agreement with their designated Organ Procurement Organization (OPO), in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waivers.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 21, 2008.

ADDRESSES: In commenting, please refer to file code CMS–1417–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1417–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1417–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses.

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786–4554.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

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

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of transplantable organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1) and our regulations at 42 CFR § 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act), and our regulations at § 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every participating hospital must have an agreement to identify potential donors only with its designated OPO.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one initially designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to comment in writing during the 60-day period beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under sections 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information that hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the request and comments received. During the review process, we may consult on an as-needed basis with the Public Health Service's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Requests

As permitted by § 486.308(e), the following three hospitals have requested waivers to work with and OPO other than the designated OPO for its area:

Northern Dutchess Hospital of Rhinebeck, New York has requested a waiver in order to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. Northern Dutchess Hospital is requesting a waiver to work with: Center for Donation & Transplant, 218 Great Oak Boulevard, Albany, NY 12204.

Dutchess Hospital's Designated OPO is: New York Organ Donor Network, 132 West 31st Street, 11th Floor, New York, NY 10001.

Methodist University Hospital of Memphis, Tennessee has requested a waiver in order to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. Methodist University Hospital is requesting a waiver to work with: Tennessee Donor Services, 1600 Hayes Street, Nashville, Tennessee 37203.

Methodist University Hospital's Designated OPO is: Mid-South Transplant Foundation, Inc., 8001 Centerview Parkway, Suite 302, Memphis, Tennessee 38018.

Le Bonheur Children's Medical Center of Memphis, Tennessee has requested a waiver in order to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. Le Bonheur Children's Medical Center is requesting a waiver to work with: Tennessee Donor Services, 1600 Hayes Street, Nashville, Tennessee 37203.

Methodist University Hospital's Designated OPO is: Mid-South Transplant Foundation, Inc., 8001 Centerview Parkway, Suite 302, Memphis, Tennessee 38018.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: August 8, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–18970 Filed 8–21–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2899–PN]

Medicare and Medicaid Programs; Application by the Accreditation Commission for Health Care for Continued Deeming Authority for Home Health Agencies

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of a deeming application from the Accreditation Commission for Health Care (ACHC) for continued recognition as a national accrediting organization for home health agencies (HHAs) that wish to participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act (the Act) requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. d.s.t. on September 21, 2008.

ADDRESSES: In commenting, please refer to file code CMS–2899–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the file code to find the document accepting comments.

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

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2899–PN, P.O. Box 8013, Baltimore, MD 21244–8013.

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

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

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2899–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636; Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

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

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a home health agency (HHA) provided certain requirements are met. Sections 1861(m) and (o), and 1891 of the Social Security Act (the Act) authorize the Secretary to establish distinct criteria for facilities seeking designation as an HHA. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at part 488. The regulations at part 484 specify the conditions that an HHA must meet in order to participate in the Medicare

program, the scope of covered services and the conditions for Medicare payment for home health care.

Generally, in order to enter into an agreement with the Medicare program, an HHA must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 484. Thereafter, the HHA is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative to surveys by State agencies, which is accreditation.

Section 1865(b)(1) of the Act provides that, if an HHA demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those HHAs as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for deeming authority under part 488, subpart A must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). Section 488.8(d)(3) requires accrediting organizations to reapply for continued deeming authority every 6 years or sooner as determined by us.

In the February 24, 2006 **Federal Register** (71 FR 9564), we published a final notice announcing our decision to approve the Accreditation Commission for Health Care (ACHC) as a recognized accreditation program for HHA's. ACHC's term of approval expires February 24, 2009.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act and § 488.8(a) of the regulations require that our findings concerning review and reapproval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's: Requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of ACHC's request for continued deeming authority for HHAs. This notice also solicits public comment on whether ACHC's requirements meet or exceed the Medicare conditions of participation for HHAs.

III. Evaluation of Deeming Authority Request

ACHC submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for HHAs. This application was determined to be complete on June 27, 2008. Under section 1865(b)(2) of the Act and § 488.8 of the regulations (Federal review of accrediting organizations), our review and evaluation of ACHC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of ACHC's standards for an HHA as compared with CMS's HHA conditions of participation.
- ACHC's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of ACHC's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ ACHC's processes and procedures for monitoring HHAs found out of compliance with ACHC's program requirements. These monitoring procedures are used only when ACHC identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.7(d).

++ ACHC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ ACHC's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of ACHC's staff and other resources, and its financial viability.

++ ACHC's capacity to adequately fund required surveys.

++ ACHC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ ACHC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

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

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35 *et seq.*).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866 (September 1993, Regulatory Planning and Review, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

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

Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 7, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–18971 Filed 8–21–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1405–N]

Medicare Program; Medicare Provider Feedback Group Town Hall Meeting—September 22, 2008

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

ACTION: Notice of meeting.

SUMMARY: This notice announces the annual Medicare Provider Feedback Group (MPFG) Town Hall meeting. This meeting is open to all Medicare fee-for-service (FFS) providers and suppliers that participate in the Medicare program, including physicians, hospitals, home health agencies, third-party billers, and interested parties, to present their individual views and opinions on selected FFS Medicare topics. In addition, we will be soliciting input on how we can improve communications to better serve the Medicare providers and suppliers.

DATES: *Meeting Date:* The Town Hall meeting announced in this notice will be held on Monday, September 22, 2008 from 2 p.m. to 4 p.m. EDT.

ADDRESSES: *Meeting Location:* The Town Hall meeting will be held in the main auditorium of the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. The meeting will also be available by teleconference.

FOR FURTHER INFORMATION CONTACT: Colette Shatto, (410) 786–6932. You may also send inquiries about this meeting via e-mail to *MFG@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Since 2005, CMS has held four Medicare Provider Feedback Group (MPFG) Town Hall meetings. The purpose of these meetings is to capture individual provider and supplier feedback on relevant Fee-For-Service (FFS) Medicare policy and operational issues. These meetings allow us to further advance our efforts to strengthen the Medicare program and enhance our relationship with providers and suppliers. The meetings also provide a venue to allow us to continue a process of communication with individual providers and suppliers through the following year.

II. Meeting Format and Agenda

The meeting will begin with an overview of the goals and objectives of the MPFG efforts to gather feedback from individual Medicare providers and suppliers. This meeting will be held on-site at CMS and by teleconference. The meeting agenda and discussion materials will be available to download by September 19, 2008. These materials can be located at *http://www.cms.hhs.gov/center/provider.asp.*

The feedback provided during this meeting will assist us as we evaluate FFS Medicare policy, operational issues, and CMS' provider and supplier communication activities. Topics to be discussed include, but are not limited to, 5010 (possible next version of HIPAA standards for claims and other transactions), Medicare Administrative Contract Transitions, and Recovery Auditing.

There will be a question and answer session that offers meeting participants an opportunity to provide feedback on how CMS services physicians, providers and suppliers, as well as make suggestions on how this process can be improved. Time for participants to ask questions or provide feedback will be limited according to the number of registered participants; however, written submissions will be accepted. Individuals who wish to provide written feedback should e-mail that feedback to Colette Shatto at *MFG@cms.hhs.gov.* Written feedback will be accepted through September 30, 2008.

Consideration will be given to feedback received on the topics discussed at the meeting, but written responses will not be provided. The meeting is open to the public, but on-site attendance is limited to space available. Registered participants from the meeting will be included in the MPFG and may be contacted throughout the year for follow-up meetings to solicit additional opinions or clarify any issues that may arise from the September 22, 2008 meeting.

III. Registration Instructions

The Division of Provider Relations and Evaluations, Provider Communications Group, Center for Medicare Management is coordinating the meeting registration. While there is no registration fee, individuals, providers, and suppliers must register to participate both on-site and by teleconference. Individuals must complete the on-line registration located at *http://registration.intercall.com/go/cms2.*

The on-line registration system will capture contact information and practice characteristics (for example, names, e-mail addresses, and provider, and supplier types). Registration will be open beginning August 29, 2008 and will close on September 17, 2008. Registration after 5 p.m. EDT on September 17, 2008 will not be accepted.

The on-line registration system will generate a confirmation page to indicate the completion of your registration. Participants should print this page as his or her registration receipt. Teleconference instructions will be issued as part of the confirmation page once participants have registered through the on-line registration instrument. If seating capacity has been reached for on-site participants, notification will be sent that the meeting has reached capacity; however, those wishing to participate may still do so by teleconference.

IV. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by 5 p.m. EDT on September 17, 2008. Individuals who have not registered by the registration deadline will not be allowed to enter the building to attend the meeting or attend the meeting by teleconference. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors will be held from 12:30 p.m. to 1:30 p.m. EDT. Participants should allow sufficient time to go through the security checkpoints. It is suggested that participants arrive at 7500 Security Boulevard no later than 1:30 p.m. EDT in order to arrive promptly at the meeting by 2 p.m.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection. In order to gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license, or

passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the CMS building and will not be permitted to attend the meeting.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the Designated Federal Officer specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by September 17, 2008.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 19, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–19564 Filed 8–21–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0419]

Draft Guidance for Industry on Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of acute bacterial exacerbations of chronic bronchitis in patients with chronic obstructive pulmonary disease (ABECB–COPD). The agency's thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of the changes in our recommendations. In addition, it will fulfill a statutory requirement enacted in the Food and Drug Administration Amendments Act of 2007 (FDAAA) to publish such a guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 20, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Steven Gitterman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6134, Silver Spring, MD 20993–0002, 301–796–1600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of ABECB–COPD. This guidance revises the draft guidance regarding ABECB published in 1998. Section 911 of FDAAA (Public Law 110–85) adds section 511 to the Federal Food, Drug, and Cosmetic Act that directs the Secretary of Health and Human Services to ''issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat * * * acute bacterial exacerbation of chronic bronchitis.''

The design of ABECB clinical trials was discussed at a meeting of the Anti-Infective Drugs Advisory Committee on February 19, 2002, and an IDSA/PhRMA/FDA workshop on November 19 and 20, 2002. In addition, other advisory committee meetings have focused on the development of specific drugs for this indication. As a result of these public discussions, as well as review of applications at FDA, the agency's thinking in this area has evolved in recent years, and this draft guidance informs sponsors of the changes in our recommendations. Specifically, this draft guidance recommends that ABECB–COPD clinical trials be designed as superiority rather than noninferiority trials, and discusses some possible study designs that might be employed in an ABECB–COPD trial designed to show superiority. This draft guidance discusses patient-reported outcome instruments for assessing clinical response, and the use of time to resolution of symptoms as a possible approach to assessing the primary endpoint in clinical studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing drugs for the treatment of ABECB–COPD. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information referred to in the guidance ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: August 13, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19490 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0447]

Achieving a Future Vision at the 2008 Parenteral Drug Association and the Food and Drug Administration Joint Regulatory Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Achieving a Future Vision at the 2008 Parenteral Drug Association and the Food and Drug Administration Joint Regulatory Conference. The topics to be discussed are: FDA's Pharmaceutical Inspectorate and the Global Harmonization Task Force; Trans Atlantic initiative; Product development; and legacy products; Supply chain; Combination products; and Recall root causes.

Date and Time: The meeting will be held on September 8 through 12, 2008, 7 a.m. to 6.

Location: The meeting will be held at Renaissance Hotel, 999 9th St., NW., Washington, DC 20001.

Contact: Wanda Neal-Ballard, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 200, Bethesda, MD 20814 or by telephone on 301–986–0293, ext. 111.

Registration and Meeting Information: See PDA Web site, *www.pda.org/pdafda2008* or contact Wanda Neal-Ballard on 301–986–0293, ext. 111. From now until August 25, 2008, registration fees are as follows: $1,600.00 for Members, $2,000.00 for Non-members, $615.00 for Government/Health Authority/Academic and $230.00 for Students. After August 25, 2008, registration fees are as follows: $1,800.00 for Members, $2,200.00 for Non-members, $700.00 for Government/Health Authority/Academic and $260.00 for Students.

If you need special accommodations due to a disability, please contact Wanda Neal-Ballard at least 7 days in advance.

Dated: August 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19491 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; California Health Interview Survey Cancer Control Module (CHIS–CCM) 2009 (NCI)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: California Health Interview Survey Cancer Control Module (CHIS–CCM) 2009. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The NCI has sponsored four Cancer Control Modules in the California Health Interview Survey (CHIS), and will be sponsoring a fifth to be administered in 2009. CHIS is a telephone survey that collects population-based, standardized health-related data to assess California's progress in meeting Healthy People 2010 objectives for the nation and the state. The CHIS sample is designed to provide statistically reliable estimates statewide, for California counties, and for California's ethnically and racially diverse population. Initiated by the UCLA Center for Health Policy Research, the California Department of Health Services, and the California Public Health Institute, the survey is funded by a number of public and private sources. It was first administered in 2001 to 55,428 adults and subsequently in 2003 to 42,043 adults, in 2005 to 43,020 adults, and in 2007 to 48,150 adults. These adults are a representative sample of California's non-institutionalized population living in households. CHIS 2009, the fifth bi-annual survey, is planned for administration to 55,000 adult Californians. This study will allow NCI to examine patterns and trends in cancer screening and follow-up, as well as to study other cancer-related topics such as tobacco control, diet, physical activity, and obesity. Additionally, CHIS is designed to be comparable to the National Health Interview Survey (NHIS) data in order to conduct comparative analyses. CHIS provides enhanced estimates for cancer risk factors and screening among racial/ethnic minority populations. *Frequency of Response:* Once. *Affected public:* Individuals or households. *Types of Respondents:* U.S. adults and adolescents (persons 12 years of age and older). The total annual burden hours requested are 3,276.94 (see Table A). The annualized cost to respondents is estimated at: $55,071.88. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE A—ANNUALIZED BURDEN ESTIMATES FOR CHIS 2009

Type of respondent	Form type	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Adults	Adult Pilot	75	1	8/60	10.00
	Adult Survey	24,000.00	1	8/60	3,200.00

TABLE A—ANNUALIZED BURDEN ESTIMATES FOR CHIS 2009—Continued

Type of respondent	Form type	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Adolescents	Adolescent Pilot	8	1	2/60	.27
	Adolescent Survey	2,000.00	1	2/60	66.67
Total		26,083			3,276.94

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nancy Breen, Ph.D., Project Officer, National Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344, Bethesda, Maryland 20852–7344, or call non-toll free number 301–496–8500 or email your request, including your address to: *breenn@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of this publication.

Dated: August 13, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison Office, National Institutes of Health.

[FR Doc. E8–19453 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Licensing and/or Cooperative Research and Development Agreement (CRADA) Opportunities—Enhanced T-cell Activation by Costimulation: A Potentially Novel Approach for the Prevention and/or Therapy of Cancer (Excluding Prostate Diseases and Melanoma) and for Infectious Diseases

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. Cooperative Research and Development Agreement (CRADA) opportunities are also available.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Mojdeh Bahar, J.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville MD 20852; *telephone:* 301/435–2950; *e-mail: baharm@mail.nih.gov*. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications. If interested in a Cooperative Research and Development Agreement (CRADA) Opportunity, please submit a statement of interest and capability to Kevin Brand, J.D., in the NCI Technology Transfer Center, 6120 Executive Boulevard, Suite 450, Rockville MD 20852; *telephone:* 301/451–4566; *e-mail: kb229t@nih.gov*.

SUPPLEMENTARY INFORMATION:

Description of Technology

Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells and not expressed or minimally expressed in normal tissues, are employed to generate a tumor specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that results in tumor destruction. The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen specific via the peptide/major histocompatibility complex and the second or ''costimulatory'' signal is required for cytokine production, proliferation, and other aspects of T-cell activation.

The present technology describes recombinant poxvirus vectors encoding at least three or more costimulatory molecules and tumor associated antigens (TAAs). The use of three costimulatory molecules such as B7.1, ICAM–1 and LFA–3 (TRICOM®) has been shown to act in synergy with several tumor antigens and antigen epitopes to activate T cells. The effects with TRICOM® were significantly greater than with one or two costimulatory molecules. Laboratory results support the greater effect of TRICOM® to activate both $CD4^+$ and $CD8^+$ T cells. The invention also describes the use of at least one target antigen or immunological epitope as an immunogen or vaccine in conjunction with TRICOM®. The antigens include but are not limited to carcinoembryonic antigen (CEA) and MUC–1. The combination of CEA, MUC–1, and TRICOM® is referred to as PANVAC®.

Availability

The technology is available for exclusive and non-exclusive license in combinations and fields of use. Some potential licensing opportunities involving recombinant poxviral vectors containing transgenes are as follows:

(1) TRICOM® (alone or with a transgene for a tumor antigen and/or an immunostimulatory molecule);

(2) The antigens only, including but not limited to CEA and MUC–1;

PANVAC®; and

(3) Recombinant fowlpox–GM–CSF.

Applications and Modality

Vector-based TRICOM® (alone or with a transgene(s) for a tumor antigen and/or an immunostimulatory molecule(s)), PANVAC® and combinations thereof can be a potential novel approach for the prevention or treatment of cancer (with the exclusion of prostate cancer, prostatic diseases, and melanoma) and infectious diseases.

Advantages

- The technology is beyond proof-of-concept, supported by laboratory results and publications.
- Phase I and Phase II clinical data available (to qualified licensees).
- Fewer validation studies are required compared to other immunotherapy related technologies.

Development Status

Phase I and Phase II results available (to qualified licensees) for poxvirus recombinants containing transgenes for TRICOM®, CEA–TRICOM®, and PANVAC®. Further clinical studies are ongoing.

Inventors

Jeffrey Schlom (NCI) *et al.* (Inventor Web page: *http://ccr.cancer.gov/Staff/staff.asp?profileid=5444*).

Publications

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Patent Status

1. U.S. Patent No. 6,969,609 issued November 29, 2005 as well as issued and pending foreign counterparts [HHS Ref. No. E–256–1998/0];

2. U.S. Patent Application No. 11/321,868 filed December 30, 2005 [HHS Ref. No. E–256–1998/1]; and

3. U.S. Patent No. 6,756,038 issued June 29, 2004 as well as issued and

pending foreign counterparts [HHS Ref. No. E–099–1996/0];

4. U.S. Patent No. 6,001,349 issued December 14, 1999 as well as issued and pending foreign counterparts [HHS Ref. No E–200–1990/3–US–01];

5. U.S. Patent No.6,165,460 issued December 26, 2000; as well as issued and pending foreign counterparts [HHS Ref. No E–200–1990/4–US–01];

6. U.S. Patent No. 7,118,738 issued October 10, 2006 as well as issued and pending foreign counterparts [HHS Ref. No E–154–1998/0–US–07];

7. PCT Application No. PCT/US97/12203 filed July 15, 1997 [HHS Ref. No E–259–1994/3–PCT–02];

8. U.S. Patent Application Nos. 10/197,127. and 08/686,280 filed July 17, 2002 and July 25, 1996 [HHS Ref. No E–259–1994/3–US–08 and /4–US–01];

9. U.S. Patent No. 6,946,133 issued September 20, 2005 as well as issued and pending foreign counterparts [HHS Ref. No E–062–1996/0–US–01];

10. U.S. Patent Application No. 11/606,929 filed December 1, 2006 [E–062–1996/0–US–11];

11. U.S. Patent Nos. 6,893,869, 6,548,068 and 6,045,802 issued May 17, 2005, April 15, 2003 and April 4, 2000 respectively, as well as issued and pending foreign counterparts [HHS Ref. Nos. E–260–1994/1–US–03, US–02, US–01]; and

12. U.S. Patent. Application No. 11/090,686 filed March 8, 2005 [HHS Ref. No E–260–1994/1–US–04].

Cooperative Research and Development Agreement (CRADA) Opportunities

A CRADA partner for the further co-development of this technology is currently being sought by the Laboratory of Tumor Immunology and Biology, Center for Cancer Research, NCI. The CRADA partner will (a) generate and characterize recombinant poxviruses expressing specific tumor-associated antigens, cytokines, and/or T-cell costimulatory factors, (b) analyze the recombinant poxviruses containing these genes with respect to appropriate expression of the encoded gene product(s), (c) supply adequate amounts of recombinant virus stocks for preclinical testing, (d) manufacture and test selected recombinant viruses for use in human clinical trials (with the exception of trials for prostatic diseases and melanoma), (e) submit Drug Master Files detailing the development, manufacture, and testing of live recombinant vaccines to support the NCI-sponsored IND and/or company-sponsored IND, (f) supply adequate amounts of clinical grade recombinant poxvirus vaccines for clinical trials conducted at the NCI Center for Cancer Research (CCR), and (g) provide adequate amounts of vaccines for extramural clinical trials, if agreed upon by the parties, and conduct clinical trials under company-sponsored or NCI-sponsored INDs. NCI will (a) provide genes of tumor-associated antigens, cytokines and other immunostimulatory molecules for incorporation into poxvirus vectors, (b) evaluate recombinant vectors in preclinical models alone and in combination therapies, and (c) conduct clinical trials (with the exception of trials for prostatic diseases and melanoma) of recombinant vaccines alone and in combination therapies.

Dated: August 14, 2008

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–19462 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council; Clinical Trials Subcommittee.

Date: September 18, 2008.

Closed: 8 a.m. to 9 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

Open: 9 a.m. to 10 a.m.

Agenda: To discuss clinical trials policy.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

Contact Person: Deborah G Hirtz, MD, Acting Director, Clinical Trials Cluster, National Institute of Neurological, Disorders and Stroke, National Institute of Health, 6001 Executive Blvd., Suite 2212, Bethesda, MD 20892, (301) 496–5821, *hirtz@ninds.nih.gov*.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.ninds.nih.gov*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to NeurologicalDisorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 15, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–19442 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the National Advisory Neurological Disorders and Stroke Council.

The meetings will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Neurological Disorders and Stroke Council, Training, Career Development, and Special Programs Subcommittees.

Date: September 17, 2008.

Time: 8 p.m. to 10 p.m.

Agenda: To discuss the training programs of the Institute.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Stephen J. Korn, PhD, Training and Special Programs Officer, National Institute of Neurological Disorders and Stroke, National Institutes of Health, 6001 Executive Blvd., Suite 2154, MSC 9527, Bethesda, MD 20892–9527, (301) 496–4188.

Name of Committee: National Advisory Neurological Disorders and Stroke Council, Basic and Preclinical Programs Subcommittee.

Date: September 18, 2008.

Time: 8 a.m. to 10 a.m.

Agenda: To discuss basic and preclinical programs policy.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 7, Bethesda, MD 20892.

Contact Person: Jill E. Heemskerk, PhD, Acting Chief, Technology Development, National Institute of Neurological Disorders and Stroke, National Institutes of Health, 6001 Executive Boulevard, Suite 2229, MSC 9527, Bethesda, MD 20892–9527, (301) 496–1779, *jh440o@nih.gov.*

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.ninds.nih.gov*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 15, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–19449 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the President's Cancer Panel.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended, because the premature disclosure of these discussions would be likely to significantly frustrate implementation of recommendations.

Name of Committee: President's Cancer Panel.

Date: September 16, 2008.

Open: September 16, 2008, 8 a.m.–4:15 p.m.

Agenda: Environmental Factors in Cancer.

Place: Hilton East Brunswick, 3 Tower Center Boulevard, East Brunswick, NJ 08816.

Closed: September 16, 2008, 4:30 p.m.–7:30 p.m.

Agenda: Discussion concerning the release of the final report and recommendations from the 2007–2008 series; discussion of testimony given in open session on Environmental Factors in Cancer; consideration of thematic concepts for the 2009/2010 series.

Place: Hilton East Brunswick, 3 Tower Center Boulevard, East Brunswick, NJ 08816.

Contact Person: Abby Sandler, Ph.D., Executive Secretary, National Cancer Institute, National Institutes of Health, Building 6116, Room 220, MSC 8349, 6116 Executive Boulevard, Bethesda, MD 20892, 301/451–9399.

Any interested person may file written comments with the committee by forwarding the comments to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/pcp/pcp.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 15, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–19448 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NIDDK.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Diabetes and Digestive and Kidney Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDDK.

Date: October 6–7, 2008.

Time: October 6, 2008, 9 a.m. to 5 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, 9S235, Bethesda, MD 20892.

Time: October 7, 2008, 9 a.m. to 4 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, 9S235, Bethesda, MD 20892.

Contact Person: Ira W. Levin, PhD, Chief, Section on Molecular Biophysics, Division of Intramural Research, National Institute of Diabetes and Digestive and Kidney Diseases, NIH, Bethesda, MD 20892, 301–496–6844, *iwl@helix.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition

Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 15, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–19450 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Workgroup Meeting; Notice Is Hereby Given of a Meeting of the Strategic Planning Implementation Workgroup (SPIWG) Organized by the Interagency Autism Coordinating Committee (IACC)

The purpose of the workgroup meeting is to discuss future budgetary requirements for the IACC Strategic Plan for Autism Spectrum Disorder (ASD) Research. The workgroup findings will be forwarded to the IACC for consideration and discussion at the next committee meeting on November 21, 2008.

Audio of this workgroup meeting will be accessible to the public via a teleconference phone link, and there will be Web-based access to information displayed at the meeting via computer/projector. Attendance at the meeting will be limited due to space available.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of Meeting: Strategic Planning Implementation Working Group.

Date: September 10, 2008.

Time: 11 a.m. to 3 p.m. EDT.

Agenda: To discuss future budgetary requirements for the IACC Strategic Plan for Autism Spectrum Disorder (ASD) Research.

Place: National Institutes of Health, Building 1, Wilson Hall, Bethesda, MD 20892.

Access Information: Conference Call and Webinar, Webinar Registration and Access Information: *https://www1.gotomeeting.com/register/550445924.* To Access the Conference Call: Dial: Number: 888–455–2920. Access Code: 3857872.

Contact Person: Azik Schwechter, Ph.D., Office of Autism Research Coordination, Office of the Director, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC Room 8203a, Bethesda, MD 20892–9669, 301–443–7163, *IACCPublicInquiries@mail.nih.gov.*

Please Note: The workgroup meeting will be open to the public through a conference call phone number and a web presentation tool on the Internet. Individuals who participate using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request at least 2 weeks prior to the meeting.

Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. There may be an opportunity for members of the public to submit written comments during the workgroup meeting through the web presentation tool. Submitted comments will be reviewed after the meeting. If you experience any technical problems with the web presentation tool, please contact GoToWebinar at (800) 263–6317. To access the web presentation tool on the Internet the following computer capabilities are required:

A. Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later;

B. Windows® 2000, XP Home, XP Pro, 2003 Server or Vista;

C. Stable 56k, cable modem, ISDN, DSL or better Internet connection;

D. Minimum of Pentium 400 with 256 MB of RAM (Recommended);

E. Java Virtual Machine enabled (Recommended).

Information about the IACC is available on the Web site: *http://www.nimh.nih.gov/research-funding/scientific-meetings/recurring-meetings/iacc/index.shtml.*

Dated: August 15, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–19455 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: Diagnostics Based on Immune Reactions to Brother of the Regulator of Imprinted Sites (BORIS)

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), announces that the Department of Health and Human Services is contemplating the grant of an exclusive license to practice the inventions embodied in PCT Application No. PCT/US2007/77281, entitled ''BORIS Isoforms and Methods of Detecting and Treating Disease'' filed August 30, 2007 (E–117–2006/0–PCT–02); EP Application No. 05799643.1, entitled ''Method of Detecting Cancer Based On Immune Reaction To BORIS'' filed September 21, 2005 (E–241–2004/0–EP–03); U.S. Application Serial No. 11/575,732, entitled ''Method of Detecting Cancer Based On Immune Reaction To BORIS'' filed March 21, 2007 (E–241–2004/0–US–04); U.S. Patent No. 7,375,206, entitled ''Brother of The Regulator of Imprinted Sites (BORIS)'' issued May 28, 2008 (E–227–2001/0–US–03); and EP Patent Application No. 03743179.8, entitled ''Brother of The Regulator of Imprinted Sites (BORIS)'' filed September 17, 2004 (E–227–2001/0–EP–04) to Wellstat Diagnostics, Inc.

The prospective exclusive territory may be worldwide, and the field of use may be limited to manufacture and sale of diagnostics for cancer and cancer predisposition.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before October 21, 2008 will be considered.

ADDRESSES: Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Mojdeh Bahar, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804. Telephone: (301) 435–2950; Facsimile: (301) 402–0220; E-mail: *baharm@od.nih.gov.*

SUPPLEMENTARY INFORMATION: The above-mentioned patent applications describe the human protein Brother of Regulator of Imprinted Sites (''BORIS''), and a method of detecting cancer by monitoring BORIS expression or by detecting anti-BORIS antibodies. Dr. Victor V. Lobanenkov and colleagues at the National Institute of Allergy and Infectious Diseases discovered BORIS and its potential application as a cancer diagnostic. BORIS is a paralog of CCCTC-binding factor (''CTCF''), a transcription factor that also functions in chromatin insulation. The amino acid sequences of BORIS and CTCF contain eleven conserved zinc fingers each of which binds to DNA. BORIS protein can be detected in cancer cells, and importantly, it is one of a few cancer-testis antigens that are immunogenic in humans.

BORIS resides in 20q13.2, a region that is commonly amplified in many human cancers. Normally, BORIS mRNA can be detected in testis, but not in other human tissues. However, BORIS mRNA is detectable in over one hundred cancer cell lines representing most of the major forms of human tumors and is also detectable in primary breast cancer tumor samples, but not in controls. BORIS protein is mis-expressed in cancer cell lines, and antibodies against BORIS have been detected in serum from patients with

gliomas, lung, breast or prostate cancers but not in serum from controls.

The correlation between cancer and BORIS expression indicates that detection of aberrantly expressed BORIS and/or anti-BORIS antibodies could serve as a method of screening or diagnosing cancer. In patients already known to have cancer, expression of BORIS could be monitored to measure a patient's response to a particular therapeutic regimen.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 14, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–19454 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Inmunotoxins as Therapeutics for Focal Muscle Spasms

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(l) and 37 CFR part 404.7(a)(l)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the invention embodied in issued U.S. Patent 6,780,413 entitled ''Immunotoxin (MAB–Ricin) for the Treatment of Focal Movement Disorders'' [HHS Ref. E–132–1996/0–US–04] to Aphrodite Therapeutics, Inc., which has offices in Vancouver, Canada. This patent has been assigned to the Government of the United States of America. There are no foreign patents or patent applications associated with this technology. There are no other U.S. Patents or Patent Applications associated with this technology.

The prospective exclusive license territory may be worldwide, and the field of use maybe limited to the development and sale of antibody conjugated toxins targeting the nicotinic acetylcholine receptors for therapeutic treatment of focal muscle spasms, as claimed in the Licensed Patent Rights.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 21, 2008 will be considered.

ADDRESSES: Requests for copy of the patent, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Betty B. Tong, PhD, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 594–6565; Facsimile: (301) 402–0220; E-mail: *tongb@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The invention describes immunotoxins and methods of using the immunotoxins for the treatment of focal muscle spasms. A specific immunotoxin covered by this technology is MAB–Ricin. The immunotoxins are targeted via an antibody that is specific to acetylcholine receptors present in large numbers on the muscle side of the neuromuscular junction, allowing the specific destruction of muscle cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 14, 2008.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E8–19463 Filed 8–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Strategic Prevention Framework State Incentive Grant (SPF SIG) Program (OMB No. 0930–0279) Revision

SAMHSA's Center for Substance Abuse Prevention (CSAP) is responsible for the evaluation instruments of the Strategic Prevention Framework State Incentive Grant (SPF SIG) Program. The program is a major national initiative designed to: (1) Prevent the onset and reduce the progression of substance abuse, including childhood and underage drinking; (2) reduce substance abuse related problems in communities; and, (3) build prevention capacity and infrastructure at the State/territory/Tribe and community levels.

Five steps comprise the SPF:

Step 1: Profile population needs, resources, and readiness to address needs and gaps.

Step 2: Mobilize and/or build capacity to address needs.

Step 3: Develop a comprehensive strategic plan.

Step 4: Implement evidence-based prevention programs, policies, and practices.

Step 5: Monitor, evaluate, sustain, and improve or replace those that fail.

An evaluation team is currently implementing a multi-method, quasi-experimental evaluation of the first two Office of Management and Budget (OMB) approved SPF SIG cohorts receiving their first year grant awards in FY 2004 and FY 2005. This is known as the Cohort 1 and 2 Cross-Site Evaluation Study, OMB–0930–0279. This 60-Day Notice invites comment on grantee-level, community-level, and participant-level data collection instruments designed for the cross-site evaluation of 16 Cohort 3 grantees receiving grants in FY 2006 and a yet-undetermined number of Cohort 4 grantees to be funded in the near future. Since the ultimate goal is to fund all eligible jurisdictions, there are no control groups at the grantee level. The purpose of cross-site evaluation is to measure the impact of community-funded grantees versus non-funded communities on SAMHSA's NOMs.

Data collected at the grantee, community, and participant levels using the three instruments will be combined in an analysis that investigates the relationship, if any, between the SPF process and substance use outcomes at individual and community levels. The instruments will be included in an OMB review package submitted immediately after the expiration of the comment period.

Grantee-Level Data Collection

Two instruments were developed for assessing grantee-level effects. Both instruments are guides for interviews that will be conducted by the grantees' evaluators twice over the life of the SPF SIG award. These instruments are modified versions of those used in the SPF SIG Cohort 1 and 2 Cross-Site Evaluation Study (OMB–0930–0279). The total burden of the original instruments has been reduced by deleting several questions and replacing the majority of open-ended questions with multiple-choice questions. The *Strategic Prevention Framework Implementation Interview Protocol* will be used to assess the relationship between SPF implementation and change in the NOMs. The *Infrastructure Instrument* will capture data to assess infrastructure change and to test the relationship of this change to outcomes.

Prevention infrastructure refers to the organizational features of the system that delivers prevention services, including all procedures related to planning, data management, workforce development, intervention implementation, evaluation and monitoring, financial management, and sustainability. The estimated annual burden for grantee-level data collection is outlined below:

GRANTEE LEVEL INSTRUMENT BURDEN ESTIMATE

Interview guide	Content description	Number of respondents	Number of responses per respondent	Burden per respondent (hrs.)	Total burden (hrs.)
SPF Implementation	SEW activities, indicators for each SPF step, including cultural competence, throughout all five steps.	32	3	2	192
State Infrastructure	Assessment of a State's progress over time toward the implementation of these best practices.	32	3	3	288
Total Burden				15	480
Average Annual Burden Over Three Years.				5	160

Community-Level Data Collection (Revision)

The Community-Level Instrument is a two-part, Web-based survey for capturing information about SPF SIG implementation at the subrecipient community level. The instrument is a modified version of the one in use in the SPF SIG Cohorts 1 and 2 Cross-Site Evaluation Study (OMB–0930–0279). The total burden of the original instrument was reduced by deleting several questions.

Part 1 of the instrument focuses on the five SPF SIG steps and efforts to ensure cultural competency throughout the SPF SIG process. Part 2 will capture data on the specific intervention(s) implemented at the community level, including both individually-focused and environmental prevention strategies. Part 2 is a modular instrument that includes separate subforms for each of the eight different intervention types. This part will be completed for each intervention implemented during the reporting period, selecting only those subforms that apply to the interventions being reported. Community partners receiving SPF SIG awards will be required to complete the entire online survey once and enter updates every six months, using a secure password system. The estimated annual burden for community-level data collection is displayed in the next table. Note that the total burden assumes an average of 15 community-level subrecipients per grantee (a total of 480 respondents), an average of three distinct interventions implemented by each community, and two survey updates per year. Additionally, some questions will be addressed only once during the data collection process and these prior responses will populate subsequent updates. As community partners work through the SPF steps, they will report only on step-related activities. For example, needs assessment activities will likely precede monitoring and evaluation activities. Thus, respondents will answer questions related to needs assessment in the first few reports but will not address monitoring and evaluation items until later in the implementation process.

COMMUNITY LEVEL INSTRUMENT BURDEN ESTIMATE

Survey section	Content description	Average burden per response (hrs.)	Number of respondents	Number of responses per respondent	Total burden (hrs.)
Reporting Period 1					
Part I, 1–235	Community Partner Activities	39.5	480	1	1896
Part II, 1–44	Prevention Intervention Information.	1.3	480	3	1872
Part II, 45–280	Intervention-Type-Specific Information.	12.6	480	3	604.8
Reporting Periods 2–6 (updates)					
Part I, 1–235	Community Partner Activities	0.91	480	5	2184
Part II, 1–44	Prevention Intervention Information.	0.2	480	15	1440
Part II, 45–280	Intervention-Type-Specific Information.	0.15	480	15	1080
Total Burden Over Six Reporting Periods.					9076.8
Average Annual Burden Over Three Years.					3025.6

Participant-Level Data Collection (New Section)

Participant-level data will be collected from all participants in direct service programs which last 30 days or more. Two instruments will be used for this purpose, one for participants aged 12–17 (youth instrument) and another for participants aged 18 or older (adult instrument). The core sections of the two instruments will be the CSAP NOMs Adult and Youth Programs Survey Forms (OMB–0930–0230).

The participant-level instruments will be administered to each participant at program entry, program exit, and six months after program exit. The following burden estimation is based on the assumption that each subrecipient community will serve 50 participants per year in direct-service interventions lasting 30 days or more, amounting to 12,000 participants per year.

PARTICIPANT LEVEL INSTRUMENT BURDEN ESTIMATE

Survey type	Number of respondents per year	Burden per respondent (hrs.)	Total annual burden (hrs.)
Baseline	12,000	0.83	9,960
Exit	10,800	0.83	8,964
Followup	8,400	0.83	6,972
Total		2.49	25,896
Average Annual Burden over Three Years			8,632

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: August 14, 2008.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. E8–19484 Filed 8–21–08; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2008–0086]

Homeland Security Advisory Council

AGENCY: Policy Directorate, DHS.

ACTION: Notice of Open Teleconference Federal Advisory Committee Meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will meet via teleconference for purposes of reviewing and reporting to the Secretary of the Department of Homeland Security the ten most pressing strategic-level challenges that will confront the next Secretary of Homeland Security.

DATES: The HSAC conference call will take place from 3 p.m. to 4 p.m. EST on Thursday, September 11, 2008. Please be advised that the meeting is scheduled for one hour and we encourage all participating members of the public to call-in at the beginning of the call.

ADDRESSES: The HSAC meeting will be held via teleconference. The dial in number is 1–800–860–2442 with a PIN code of 82242#. Members of the public interested in participating in this teleconference meeting may do so by following the process outlined below (see ''Public Attendance'').

If you desire to submit written comments, they must be submitted by September 5, 2008. Comments must be identified by DHS–2008–0086 and may be submitted by *one* of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *E-mail: HSAC@dhs.gov.* Include docket number in the subject line of the message.

• *Fax:* (202) 282–9207.

• *Mail:* Homeland Security Advisory Council, Department of Homeland Security, Mailstop 0850, 245 Murray Lane, SW., Washington, DC 20528.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and DHS–2008–0086, the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the DHS Homeland Security Advisory Council, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Myers, Homeland Security Advisory Council, Washington, DC 20528, (202) 447–3135, *HSAC@dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). The HSAC provides independent advice to the Secretary of the Department of Homeland Security to aide in the creation and implementation of critical and actionable policies and capabilities across the spectrum of homeland security operations. The HSAC shall periodically report, as requested, to the Secretary, on such matters. The HSAC serves as an advisory body with the goal of providing strategic, timely and actionable advice upon the request of the Secretary.

The HSAC will meet to review the ten most pressing strategic-level challenges that face the incoming Secretary of Homeland Security.

Public Participation: Members of the public may register to participate in this HSAC teleconference via the procedures that follow. Each individual must provide his or her full legal name and e-mail address and phone number no later than 5 p.m. EST., September 8, 2008, to Jennifer Myers or a staff member of the HSAC via e-mail at *HSAC@dhs.gov* or via phone at (202) 447–3135. HSAC conference call details will be provided to interested members of the public.

Information on Services for Individuals with Disabilities: For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact Jennifer Myers as soon as possible.

Dated: August 18, 2008.

Jeffrey D. Stern,

Executive Director, Homeland Security Advisory Committees.

[FR Doc. E8–19557 Filed 8–21–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2004–19621]

Dry Cargo Residue Discharges in the Great Lakes

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability and request for comments.

SUMMARY: The Coast Guard announces the availability of the Final Environmental Impact Statement (FEIS) which provides an assessment of the potential environmental impacts associated with the proposed regulation of residue resulting from the shipping of dry cargo on the Great Lakes. We request your comments on the Final Environmental Impact Statement (FEIS).

DATES: Comments and related material must reach the Docket Management Facility on or before September 22, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2004–19621 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Online: *http://www.regulations.gov.*

(2) Mail: Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) Hand delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) Fax: 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on the Final Environmental Impact Statement (FEIS), please contact Mr. Greg Kirkbride, U.S Coast Guard, telephone 202–372–1479 or e-mail *Gregory.B.Kirkbride@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

Public Participation and Request for Comments

We encourage you to submit comments and related material on the Final Environmental Impact Statement (FEIS) for Dry Cargo Residue Discharges in the Great Lakes. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Submitting comments: If you submit a comment, please include the docket number for this notice (USCG–2004–19621), and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Viewing the comments and FEIS: To view the comments and Final Environmental Impact Statement (FEIS) go to *http://www.regulations.gov* at any time. Enter the docket number for this notice (USCG–2004–19621) in the Search box, and click ''Go >>.'' If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act system of records notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

Background and Purpose

The Final Environmental Impact Statement (FEIS) provides an assessment of the potential environmental impacts associated with the proposed regulation of residue resulting from the shipping of dry cargo on the Great Lakes. The preferred alternative would amend Coast Guard regulations in accordance with an existing policy that allows the discharge of nontoxic and nonhazardous bulk dry cargo residues in limited areas in the Great Lakes, with new requirements for recordkeeping and new designated special areas where discharges would be prohibited. The USCG has the authority to regulate such discharges on the Great Lakes under Section 623 of Public Law 108–293.

Dated: August 15, 2008.

Howard L. Hime,

Acting Director of Commercial Regulations and Standards, United States Coast Guard.

[FR Doc. E8–19525 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2008–0778]

Lower Mississippi River Waterway Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Lower Mississippi River Waterway Safety Advisory Committee will meet in New Orleans to discuss various issues relating to navigational safety on the Lower Mississippi River and related waterways. This meeting will be open to the public.

DATES: The Committee will meet on Thursday, September 25th, 2008 from 9 a.m. to 12 p.m. This meeting may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before September 12, 2008. Requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before September 12, 2008.

ADDRESSES: The Committee will meet at the New Orleans Yacht Club, 403 North Roadway West End, New Orleans, LA 70124. Send written material and requests to make oral presentations to Sector Commander, Designated Federal Officer (DFO) of Lower Mississippi River Waterway Safety Advisory Committee, USCG Sector New Orleans ATTN: Waterways Management, 1615 Poydras St., New Orleans, LA 70112.

FOR FURTHER INFORMATION CONTACT: CWO3 David Chapman, Assistant to DFO of Lower Mississippi River Waterway Safety Advisory Committee, telephone 504–565–5103.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463).

Agenda of Meeting

The agenda for the September 25, 2008 Committee meeting is as follows:

(1) Introduction of committee members.

(2) Opening Remarks.

(3) Approval of the June 26, 2008 minutes.

(4) Old Business.

(a) Captain of the Port status report.

(b) VTS update report.

(c) Subcommittee/Working Groups update reports.

(5) Adjournment.

Procedural

This meeting is open to the public. Please note that the meeting may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at a meeting, please notify the DFO no later than September 12, 2008. Written material for distribution at a meeting should reach the Coast Guard no later than September 12, 2008. If you would like a copy of your material distributed to each member of the committee in advance of a meeting, please submit 25 copies to the DFO no later than September 12, 2008.

Information on Services for Individuals with Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the DFO as soon as possible.

Dated: July 28, 2008.

Joel R. Whitehead,

Rear Admiral, U.S. Coast Guard Commander, Eighth Coast Guard District.

[FR Doc. E8–19527 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2008–0816]

Merchant Marine Personnel Advisory Committee; Meetings

AGENCY: Coast Guard, DHS.

ACTION: Notice of meetings.

SUMMARY: The Merchant Marine Personnel Advisory Committee (MERPAC) will meet in Nashville, TN, to discuss various issues relating to the training and fitness of merchant marine personnel. These meetings will be open to the public.

DATES: MERPAC will meet on Tuesday, September 23, 2008, and Wednesday, September 24, 2008, from 8 a.m. until 4 p.m. These meetings may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before September 10, 2008. Requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before September 10, 2008.

ADDRESSES: The Committee will meet at the Innovation Center at Vanderbilt University Center for Better Health, 3401 West End Avenue, Suite 100, Nashville, TN. Send written material and requests to make oral presentations to Captain Michael Blair, Designated Federal Officer (DFO) of MERPAC, at Commandant (CG–5221), U.S. Coast Guard, 2100 Second St., SW., Washington, DC 20593–0001. This notice, as well as all task statements discussed in this notice, may be viewed in our online docket, USCG–2008–0816, at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Gould, Assistant to the DFO of MERPAC, at 202–372–1409.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463).

Agenda of Meeting

The agenda for the September 23, 2008, Committee meeting is as follows:

(1) The full committee will meet to discuss the objectives for the meeting.

(2) Working groups addressing the following task statements may meet to deliberate—

(a) Task Statement 30, concerning ''Utilizing Military Sea Service for STCW Certifications'';

(b) Task Statement 58, concerning ''Stakeholder Communications During MLD Program Restructuring and Centralization''; and

(c) Task Statement 64, concerning ''Recommendations on areas in the STCW Convention and the STCW Code identified for comprehensive review''.

(3) New working groups may be formed to address issues proposed by the Coast Guard, MERPAC members, or the public.

(4) At the end of the day, the working groups will make a report to the full committee on what has been accomplished in their meetings. No action will be taken on these reports on this date.

The agenda for the September 24, 2008, Committee meeting is as follows:

(1) Introduction;

(2) Working Groups' Reports; and

(3) Other items which may be discussed:

(a) Standing Committee—Prevention Through People.

(b) Briefings concerning ongoing projects of interest to MERPAC.

(c) Other items brought up for discussion by the Committee or the public.

(4) At the end of the day, the working groups will make a report and, if applicable, recommendations for the full committee to consider for presentation to the Coast Guard. Official action on these recommendations may be taken on this date.

Procedural

These meetings will be open to the public. Please note that the meetings may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meetings. If you would like to make an oral presentation at a meeting, please notify the DFO no later than September 10, 2008. Written material for distribution at a meeting should reach the Coast Guard no later than September 10, 2008. If you would like a copy of your material distributed to each member of the committee in advance of a meeting, please submit 25 copies to the DFO no later than September 10, 2008.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meetings, contact the DFO as soon as possible.

Dated: August 7, 2008.

J. G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. E8–19524 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 30-day notice and request for comments; Revision of a currently approved collection, OMB No. 1660–0017, FEMA Forms 90–49, 90–91, 90–91A, 90–91B, 90–91C, 90–91D, 90–120, 90–121, 90–123, 90–124, 90–125, 90–126, 90–127, and 90–128.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use. FEMA is revising this collection to include the increase in public assistance requests anticipated due to the increase in number and scope of disaster declarations.

Collection of Information

Title: Public Assistance Progress Report and Program Forms.

OMB Number: 1660–0017.

Abstract: FEMA is collecting information from affected public of state, local and tribal governments that requests funds to provide services to the public after a disaster occurs. FEMA will be provided documentation that makes known the request for a grant, the worksheets that provide details on how the grants will be used, where the grant monies will be utilized, and the resources used in providing the assistance. Data from this collection will directly result in a determination of the awarding of grant monies for public assistance to a state.

Affected Public: State, local and tribal governments.

Number of Respondents: 53. The total number of respondents of 5,070 previously reported in the 60-day **Federal Register** Notice at 73 FR 27546, May 13, 2008 was incorrectly identified.

Estimated Time per Respondent: 3,489. The estimated time per respondent of 134.25 hours previously reported in the 60-day **Federal Register** Notice at 73 FR 27546, May 13, 2008 is now corrected due to the change in the number of respondents.

Estimated Total Annual Burden Hours: 139,222. The total annual burden hours of 134,562 previously reported in the 60-day **Federal Register** Notice at 73 FR 27546, May 13, 2008 has been increased.

Frequency of Response: On occasion.

Comments: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–6974. Comments must be submitted on or before September 22, 2008.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street, SW., Washington, DC 20472, Mail Drop Room 301, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections@dhs.gov.*

Dated: August 14, 2008.

John A. Sharetts-Sullivan,

Director, Records Management Division, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E8–19605 Filed 8–21–08; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5187–N–51]

Energy Efficient Mortgages

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

Lenders provide information required to determine the eligibility of mortgage to be insured under Section 513 of the Housing and Community Development Act of 1992 (Section 106 of the Energy Policy Act of 1992).

DATES: *Comments Due Date: September 22, 2008.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2502–0561) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; *fax:* 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Lillian Deitzer, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Lillian Deitzer at *Lillian_L._Deitzer@HUD.gov* or telephone (202) 402–8048. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Deitzer.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Energy Efficient Mortgages.

OMB Approval Number: 2502–0561.

Form Numbers: HUD–92903.

Description of the Need for the Information and its Proposed Use: Lenders provide information required to determine the eligibility of mortgage to be insured under Section 513 of the Housing and Community Development Act of 1992 (Section 106 of the Energy Policy Act of 1992).

Frequency of Submission: On occasion.

	Number of respondents	Annual responses	x	Hours per response	=	Burden hours
Reporting Burden	600	3.5		1.107		2,325

Total Estimated Burden Hours: 2,325.

Status: Extension of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: August 14, 2008

Lillian L. Deitzer,

Departmental Paperwork Reduction Act Officer, Office of the Chief Information Officer.

[FR Doc. E8–19574 Filed 8–21–08; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5186–N–34]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

DATES: *Effective Date:* August 22, 2008.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7262, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: August 14, 2008.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

[FR Doc. E8–19212 Filed 8–21–08; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–IA–2008–N0214; 96300–1671–0000–P5]

Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits for endangered species and/or marine mammals.

SUMMARY: The following permits were issued.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 212, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on the dates below, as authorized by the provisions of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and/or the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service issued the requested permits subject to certain conditions set forth therein. For each permit for an endangered species, the Service found that (1) The application was filed in good faith, (2) the granted permit would not operate to the disadvantage of the endangered species, and (3) the granted permit would be consistent with the purposes and policy set forth in Section 2 of the

Endangered Species Act of 1973, as amended.

Endangered Species

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
171630	Cincinnati Zoo & Botanical Garden	73 FR 21980; April 23, 2008	June 27, 2008.
180709	Dr. M.K. Gonder, Univ., at Albany, SUNY, NY	73 FR 29144; May 20, 2008	July 25, 2008.
181813	Conservators' Center, Inc	73 FR 31709; June 3, 2008	July 17, 2008.

Endangered Marine Mammals

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
032027 & 186914.	Monterey Bay Aquarium	72 FR 70339; December 11, 2007 (both permits were published in one notice for PRT–032027).	July 25, 2008.
690038	U.S. Geological Survey, Alaska Science Center	73 FR 36891; June 30, 2008	July 31, 2008.

Dated: August 1, 2008.

Lisa J. Lierheimer,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E8–19521 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–IA–2008–N0215; 96300–1671–0000–P5]

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species.

DATES: Written data, comments or requests must be received by September 22, 2008.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 212, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following applications for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

Applicant: The Phoenix Zoo, Phoenix, AZ, PRT–185747.

The applicant requests a permit to import one male jaguar (*Panthera onca*) from Centro Ecologico de Sonora, Mexico, for the purpose of scientific research and enhancement of the survival of the species.

Applicant: Wildlife Conservation Society, New York, NY, PRT–184950.

The applicant requests a permit to import one captive born male snow leopard (*Uncia uncia*) from the Tierpark Berlin, Berlin, Germany, for the purpose of enhancement of the survival of the species.

Applicant: John E. Yeagle II, Stansbury, UT, PRT–181041.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Hawthorn Corporation, Grayslake, IL, PRT–182592, 182594, 182595, 182596, 058658, 058659, 058660, 058662, 058663, 058664, 058665, 058666, 058667, 058668, 058669, 058681, 058683, 058685, 058736, and 058780.

The applicant requests permits to re-issue and issue for export/re-export and re-import tigers (*Panthera tigris*) to worldwide locations for the purpose of enhancement of the species through conservation education. The permit numbers and animals are: [New—182592, Sherkan; 182594, Sissy; 182595, Java2; 182596, Bo; Re-issue permits—058658, Sampson; 058659, Neena; 058660, Samira; 058662, Tibor; 058663, Delhi; 058664, Bihar; 058665, Jasmine; 058666, Kiki; 058667, Nakita; 058668, Vijay; 058669, Fabra; 058681, Obi; 058683, Amira; 058685, Mona; 058736, Ravi; and 058780, Ceasar]. This notification covers activities to be conducted by the applicant over a three-year period and the import of any potential progeny born while overseas.

Dated: August 1, 2008.

Lisa J. Lierheimer,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E8–19522 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–IA–2008–N0209; 96300–1671–0000–P5]

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species.

DATES: Written data, comments or requests must be received by September 22, 2008.

ADDRESSES: Documents and other information submitted with these

applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 212, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following applications for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

Applicant: U.S. Fish and Wildlife Service, National Fish and Wildlife Forensics Laboratory, Ashland, OR, PRT–053639.

The applicant requests renewal of a permit to export/re-export and import/re-import any endangered or threatened species for the explicit purpose of forensics activities which will directly or indirectly enhance the survival of the species in the wild. This notification covers activities to be conducted by the applicant over a five-year period.

Applicant: Metro Richmond Zoo, Moseley, VA, PRT–189831.

The applicant requests a permit to import two male captive-bred cheetahs (*Acinonyx jubatus*) from the De Wildt Cheetah Breeding Center, South Africa for the purpose of enhancement of the survival of the species.

Applicant: Cincinnati Zoo, Cincinnati, OH, PRT–185761.

The applicant requests a permit to import various biological samples from captive-held and wild Sumatran rhinoceros (*Dicerorhinus sumatrensis*) from the Sumatran Rhino Sanctuary, Indonesia for the purpose of scientific research and veterinary health evaluation. This notification covers activities to be conducted by the applicant over a five year period.

Applicant: Martin K. Slaugh, Salt Lake City, UT, PRT–189851.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Dated: July 25, 2008.

Lisa J. Lierheimer,

Senior Permit Biologist, Branch of Permits, Division Management Authority.

[FR Doc. E8–19523 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–010–1990–GN; 08–08807; TAS: 14X1109]

Notice of Availability of Draft Supplemental Environmental Impact Statement for the Betze Pit Expansion Project, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et seq.*), the Bureau of Land Management (BLM), Elko District Office has prepared a Draft Supplemental Environmental Impact Statement (DSEIS) to expand the Betze Pit at an open pit gold mine in Nevada; and by this Notice is announcing the opening of the comment period.

DATES: To ensure comments will be considered, the BLM must receive written comments on the Betze Pit Expansion Project DSEIS within 45 days following the date the Environmental Protection Agency publishes the Notice of Availability in the **Federal Register**. The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media news releases and/or mailings.

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

—*E-mail: eiscommentselko@nv.blm.gov*.

—*Fax:* (775) 753–0255.

—*Mail:* Attention Kirk Laird, Project Manager, BLM Elko District Office, 3900 East Idaho Street, Elko, NV 89801.

Copies of the Betze Pit Expansion Project DSEIS are available in the BLM Elko District Office, at the above address and on the internet site at: *http://www.blm.gov/nv/st/en/fo/elko_field_office.html.*

FOR FURTHER INFORMATION CONTACT: For further information or to have your name added to the mailing list, contact Kirk Laird, Project Manager, BLM Elko District Office, 3900 East Idaho Street, Elko, NV 89801 (775) 753–0200, or e-mail to: *Kirk_Laird@blm.gov*.

SUPPLEMENTARY INFORMATION: The Betze Pit Expansion Project DSEIS is an amendment to the Betze Project Plan of Operations for an ongoing open pit mine on the Carlin Trend in Eureka and Elko counties, Nevada. The Preferred Alternative of the DSEIS includes the Proposed Action of expanding the existing open pit and constructing a new waste rock and tailings facility. Current mining operations at the Betze Project are expected to end in 2011, with processing operations ending in 2020. The Proposed Action in the Preferred Alternative of the Betze Pit Expansion Project DSEIS would extend mining for 4 years and processing for 5 years. BLM's preferred alternative would also maximize mule deer corridor access in the vicinity of the Clydesdale Waste Rock Facility. Other alternatives include the No-Action Alternative continuing mining as currently approved without approving the expansion and a third Alternative denying the construction of the new Clydesdale Waste Rock Facility in favor of continued expansion of the existing Bazza Waste Rock Facility. A cumulative impacts study and supplemental EIS completed in 2000 and 2002 addressed groundwater pumping/dewatering issues for the Betze Pit, and pumping will continue whether or not expansion is approved. Major issues are impacts of current and proposed operations on mule deer migration routes, potential changes to the post-mining pit lake chemistry, air quality including increased greenhouse gas and mercury emissions/deposition, and sustaining benefits of mining on the local economy.

Please note that public comments and information submitted including names, street addresses, and email addresses of respondents will be available for public review and disclosure at the above address during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6.

Tom Warren,

Acting District Manager.

[FR Doc. E8–19396 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–100–08–1610–DQ]

Notice of Availability of the Pinedale Proposed Resource Management Plan and Final Environmental Impact Statement, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with of the National Environmental Policy Act of 1969 and the Federal Land Policy and Management Act of 1976, the Bureau of Land Management (BLM) and its cooperating agencies, have prepared a Proposed Resource Management Plan/Final Environmental Impact Statement (PRMP/FEIS) for the Pinedale Field Office.

DATES: The BLM Planning regulations (43 CFR 1610.5–2) state that any person who meets the conditions as described in the regulations may protest the BLM's Proposed RMP. A person who meets the conditions and files a protest must file the protest within 30 days of the date that the Environmental Protection Agency publishes this notice in the **Federal Register**.

ADDRESSES: Copies of the Pinedale PRMP/FEIS have been sent to affected Federal, state, and local government agencies and to interested parties. Copies of the PRMP/FEIS will be available for public inspection at the following locations:

- Bureau of Land Management, Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming 82003.
- Bureau of Land Management, Pinedale Field Office, 1625 W Pine Street, Pinedale, Wyoming 82941.

Interested persons may also review the PRMP/FEIS on the Internet at *http://www.blm.gov/rmp/wy/pinedale.* All protests must be in writing and mailed to the following addresses:

Regular Mail: Director (210), *Attention:* Brenda Williams, P.O. Box 66538, Washington, DC 20035.

Overnight Mail: Director (210), Attention: Brenda Williams, 1620 L Street, N.W., Suite 1075, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Chuck Otto, Field Manager, or Kellie Roadifer, Pinedale RMP Team Leader, 1625 W Pine Street, Pinedale, Wyoming 82941, or by telephone at (307) 367–5309.

SUPPLEMENTARY INFORMATION: The Pinedale Field Office planning area includes public land and federal mineral ownership in Sublette and Lincoln Counties, Wyoming. The area includes approximately 923,000 acres of BLM-administered surface lands and approximately 1,199,000 acres of Federal mineral estate under Federal, state, and private surface.

The Draft RMP/Draft EIS was made available for public review and comment for a 121-day period beginning on February 16, 2007. The Draft RMP/Draft EIS described and analyzed four alternatives for the management of the public lands and resources, including the Federal mineral estate administered by the BLM Pinedale Field Office:

Alternative 1 (No Action): Continues to balance the use and development of resources under current management guidance;

Alternative 2: Provides development and use opportunities while minimizing adverse impacts to cultural and natural resources;

Alternative 3: Focuses on greater conservation of natural and cultural resources while providing for compatible development and use; and

Alternative 4 (Agency Preferred Alternative): Provides development opportunities while protecting sensitive resources.

The key issues addressed by the alternatives are: (1) Development of energy resources and minerals; (2) special management designations; (3) public access and transportation planning; (4) wildland-urban interface; (5) management of special status species; (6) water quality; (7) vegetation management; (8) recreation activities; (9) cultural resources management; (10) air quality; and (11) wildlife management.

The Draft RMP/Draft EIS included recommendations regarding Areas of Critical Environmental Concern (ACECs). While the Draft RMP/EIS fully documented the ACECs considered, to ensure that BLM provided the public with the required 60-day review and comment period as required by 43 CFR 1610.7–2, the BLM published a notice of supplemental information describing the proposed ACECs and associated values and use limitations in the **Federal Register** on February 21, 2008.

There are two ACECs in the existing Pinedale Field Office land use plan (1988): Rock Creek ACEC (5,300 acres) and Beaver Creek ACEC (3,590 acres). There are 6 potential new ACECs proposed in the Draft RMP/EIS. The ACECs are:

- *Trapper's Point ACEC (550 acres [Alternative 2], 4,000 acres [Alternative 4], or 9,540 acres [Alternative 3]):* Values of concern are big game migration corridors, cultural and historic properties, and livestock trailing. Within this ACEC, fence construction and surface disturbing activities would be prohibited with the exception of activities designed to increase big game migration viability. The ACEC would be unavailable for oil and gas leasing. Off-road vehicle use would be restricted to designated roads and trails and subject to a seasonal closure from November 15 through April 30 annually.
- *New Fork Potholes ACEC (1,800 acres [Alternatives 3 and 4]):* Values of concern are waterfowl, trumpeter swan, and riparian habitats. With the exception of those that would benefit wildlife habitat, surface disturbing activities would be prohibited. The ACEC would be unavailable for oil and gas leasing. Off-road vehicle use would be restricted to designated roads and trails.
- *Upper Green River ACEC (12,270 acres [Alternative 3]):* Values of concern are big game migration routes and migration bottlenecks, and high scenic and recreational values. The ACEC would be unavailable for oil and gas leasing. Off-road vehicle use would be restricted to designated roads and trails, and no net increase in miles of roads would be allowed.
- *White-Tailed Prairie Dog ACEC (no acreage estimate available [Alternative 3]):* The White-Tailed Prairie Dog (WTPD) ACEC would not have a specific area but would involve a number of townships where WTPD habitat might be found in future surveys. The value of concern is habitat for the WTPD. Surveys for prairie dog presence would be required prior to authorizing any activities. Anti-raptor perching devices would be required on any above-ground facilities located within 1/4 mile of WTPD towns greater than 12.5 acres in size, and surface-disturbing activities would be prohibited in these towns. Off-road vehicle use would be limited to designated roads and trails, and poisoning of prairie dogs would be prohibited except in cases of health and safety emergencies.
- *Ross Butte ACEC (35,670 acres [Alternative 3]):* Values of concern are significant cultural resources, archeological landscapes and Native

American sacred sites; a unique community of Wyoming sensitive plant species; high-quality paleontological resources; open space and dispersed recreation opportunities; and unique geology and unstable soils. The ACEC would be unavailable for oil and gas leasing and closed to the placement of new communication sites. Off-road vehicle use would be limited to designated roads and trails. Surface occupancy and disturbance would be prohibited on erosive soils, sensitive plant species habitats, and on slopes greater than 10 percent.

• *CCC Ponds ACEC (5,530 acres [Alternative 3]):* Values of concern are a wildlife migration bottleneck on a well-defined mule deer migration route and recreational values including a developed, non-motorized trail system, fishing ponds, and interpretive facilities. The ACEC would be unavailable for oil and gas leasing and would be closed to mineral location and land disposal. Off-road vehicle use would be limited to designated roads and trails.

Alternative 1 proposes to maintain the status of the two existing ACECs identified in the 1988 Pinedale RMP. Alternative 2 proposes to eliminate the two existing ACECs, and establish a new ACEC at Trapper's Point (550 acres). Alternative 3 proposes to maintain the existing Rock Creek and Beaver Creek ACECs, and establish all of the new ACECs listed above (6), for a total of eight ACECs.

As a result of public scoping and the alternative development process, Alternative 4 (Agency Preferred Alternative) proposes the following ACECs: Maintain the status of one existing ACEC (Beaver Creek); maintain and reduce slightly in size one existing ACEC (Rock Creek); and establish two new ACECs: Trapper's Point (4,000 acres) and New Fork Potholes (1,800 acres).

Comments received on the Draft RMP/EIS from the public and internal BLM review comments were incorporated into the proposed plan. Public comments resulted in the addition of clarifying text but did not significantly change proposed land use decisions. After careful consideration of both public and internal comments received on the Draft RMP/EIS, adjustments and clarifications have been made to Alternative 4, the Preferred Alternative. As modified, Alternative 4 is now presented as the Pinedale Proposed RMP in the Final EIS.

Instructions for filing a protest with the Director of the BLM regarding the PRMP/FEIS may be found in the Dear Reader Letter of the Pinedale PRMP/FEIS and at 43 CFR 1610.5. E-mail and faxed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular or overnight mail postmarked by the close of the protest period. Under those conditions, the BLM will consider the e-mail or faxed protests as an advance copy and it will receive full consideration. If you wish to provide the BLM with such advance notification, please direct faxed protests to the attention of the BLM protest coordinator at (202) 557–3599, and e-mails to *Brenda_Hudgens-Williams@blm.gov*. All protests, including the follow-up letter (if e-mailing or faxing) must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section above. Before including your phone number, e-mail address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly availability at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Jamie E. Connell,

Acting Associate State Director.

[FR Doc. E8–19534 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–080–1610–010J]

Notice of Availability of Vernal Field Office Proposed Resource Management Plan and Final Environmental Impact Statement (PRMP/FEIS)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 and the Federal Land Policy and Management Act of 1976, the Bureau of Land Management (BLM) has prepared a Proposed Resource Management Plan/Final Environmental Impact Statement (PRMP/FEIS) for the Vernal Field Office.

DATES: The BLM planning regulations (43 CFR 1610.5–2) state that any person who meets the conditions as described in the regulations may protest the BLM's PRMP/FEIS. A person who meets the conditions and files a protest must file the protest within 30 days of the date that the Environmental Protection Agency publishes this notice in the **Federal Register**.

ADDRESSES: Copies of the Vernal Field Office PRMP/FEIS were sent to affected Federal, state, and local government agencies and to interested parties. Copies of the PRMP/FEIS are available for public inspection at:

Vernal Field Office, 170 South 500 East, Vernal, UT 84078

Utah State Office, 440 West 200 South, Salt Lake City, UT 84145

Interested persons may also review the PRMP/FEIS on the Internet at *http://www.blm.gov/ut/st/en/fo/vernal/planning.html.* All protests must be in writing and mailed to the following addresses:

Regular Mail: BLM Director (210), Attention: Brenda Hudgens-Williams, P.O. Box 66538, Washington, DC 20035

Overnight Mail: BLM Director (210), Attention: Brenda Hudgens-Williams, 1620 L Street, NW., Suite 1075, Washington, DC 20036.

FOR FURTHER INFORMATION, CONTACT: Kelly Buckner, Vernal Field Office, 170 South 500 East, Vernal, UT 84078; phone: (435) 781–4400; or e-mail at: *Kelly_Buckner@blm.gov*.

SUPPLEMENTARY INFORMATION: The Vernal RMP planning area is located in northeast Utah. The BLM administers approximately 1.7 million acres of surface estate and 2.8 million acres of Federal mineral estate within the planning area.

The Vernal RMP will provide future broad-scale management direction for land use allocations and allowable uses on public lands within the planning area. Implementation of the decisions of the PRMP/FEIS would apply only to BLM-administered public lands and Federal mineral estate. In the Vernal Field Office Draft RMP/EIS (DRMP/DEIS), which was released for a 90-day public review and comment period in January 2005, four alternatives were analyzed, including a No Action alternative. These alternatives were developed through issue identification during the scoping process. Such issues included: special designations (ACECs and WSRs), minerals and energy development, and recreational (OHV) use. In October 2007 a Supplemental DEIS was issued which considered an additional alternative emphasizing the protection of non-WSA lands with Wilderness Characteristics.

The PRMP/FEIS would designate no new Areas of Critical Environmental Concern (ACECs), and the continuation of six existing ACECs, totaling 123,227

acres. Resource use limitations that apply to the proposed ACECs include a range of different prescriptions as described in Table 1 below.

TABLE 1—EVALUATION OF AREAS OF CRITICAL ENVIRONMENTAL CONCERN

Area name	Values of concern	Resource use limitations	Acres
Browns Park	Cultural, wildlife, habitat, and scenic views.	Closed to OHV use, or limited to designated routes	18,474
Red Mountain—Dry Fork	Watershed, relict vegetation, and big game habitat.	No surface occupancy, or timing/controlled surface use for oil and gas; OHV use limited to designated routes.	24,285
Nine-Mile Canyon	Cultural, and special status plant species.	The area would be open subject to standard lease terms or managed as NSO for oil and gas leasing; OHV use would be limited to designated routes.	44,181
Lears Canyon	Relict vegetation	No surface occupancy for oil and gas, closed to mineral material sales.	1,375
Pariette	Wetland, wildlife, and plant habitat.	No surface occupancy for oil and gas, closed to mineral material sales.	10,437
Red Creek	Watershed and wildlife habitat	No surface occupancy and controlled surface use; OHV use is limited to designated routes.	24,475

Comments on the Vernal Field Office DRMP/DEIS received from the public and internal BLM review were considered and incorporated as appropriate into the PRMP/FEIS. Public comments resulted in the addition of clarifying text, but did not significantly change proposed land use plan decisions.

Instructions for filing a protest with the Director of the BLM regarding the PRMP/FEIS may be found in the Dear Reader Letter of the PRMP/FEIS and at 43 CFR 1610.5–2.

E-mail and faxed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular or overnight mail postmarked by the close of the protest period. Under these conditions, the BLM will consider the e-mail or faxed protest as an advance copy and it will receive full consideration. If you wish to provide the BLM with such advance notification, please direct faxed protests to the attention of the BLM protest coordinator at 202–452–5112, and e-mails to *Brenda_Hudgens-Williams@blm.gov*.

All protests, including the follow-up letter (if e-mailing or faxing) must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section above.

Before including your phone number, e-mail address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 43 CFR 1610.2, 43 CFR 1610.5–1.

Selma Sierra,

Utah State Director.

[FR Doc. E8–19394 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–090–08–1610–DQ]

Notice of Availability of the Kemmerer Proposed Resource Management Plan and Final Environmental Impact Statement, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 and the Federal Land Policy and Management Act of 1976, the Bureau of Land Management (BLM) with its cooperating agencies has prepared a Proposed Resource Management Plan/Final Environmental Impact Statement (PRMP/FEIS) for the Kemmerer Field Office planning area.

DATES: BLM planning regulations (43 CFR 1610.5–2) state that any person who meets the conditions as described in the regulations may protest the BLM's Proposed RMP. A person who meets the conditions and files a protest must file the protest within 30 days of the date that the Environmental Protection Agency publishes its notice of availability in the **Federal Register**.

ADDRESSES: Copies of the Kemmerer PRMP/FEIS have been sent to affected Federal, State, and local government agencies and to interested parties. Copies of the PRMP/FEIS are available for public inspection at the following locations:

Bureau of Land Management, Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming 82009

Bureau of Land Management, Kemmerer Field Office, 312 HWY 189 N, Kemmerer, Wyoming 83101

Interested persons may also review the PRMP/FEIS on the Internet at *http://www.blm.gov.rmp/kemmerer*. All protests must be in writing and mailed to one of the following addresses:

Regular Mail: Director (210), Attention: Brenda Williams, P.O. Box 66538, Washington, DC 20036.

Overnight Mail: Director (210), Attention: Brenda Williams, 1620 L Street, NW., Suite 1075, Washington, DC 20035.

FOR FURTHER INFORMATION CONTACT: Michele Easley, RMP Team Leader, BLM Kemmerer Field Office, 312 HWY 189 N, Kemmerer, Wyoming 83101; telephone—(307) 828–4524; e-mail *Kemmerer_wymail@blm.gov* with ''Kemmerer RMP'' in the subject line.

SUPPLEMENTARY INFORMATION: The Kemmerer Field Office planning area is located in Lincoln, Uinta, and Sweetwater Counties, Wyoming. It includes approximately 1.4 million acres of public land surface and 1.6 million acres of Federal mineral estate administered by the BLM.

The Draft RMP/EIS was made available for public review for a 90-day period on July 13, 2007. The Draft RMP/EIS described and analyzed four alternatives for the management of the public lands and resources, including the Federal mineral estate, administered by the BLM Kemmerer Field Office:

Alternative A: (No Action): Continuation of the current management goals, objectives, and direction specified in the Kemmerer RMP and ROD (1986).

Alternative B: Provide a high level of environmental protection for wildlife habitat and other resource values, while allowing the production of resource commodities.

Alternative C: Maximize the production of resource commodities while providing an adequate level of environmental protection for other resources.

Alternative D: (BLM's Preferred Alternative): Optimize the mix of resource outputs, including production of resource commodities and wildlife habitat, while providing enhancement of environmental protection for all resources.

The key issues addressed by the alternatives are: (1) Development of domestic energy sources, including wind power; (2) off highway vehicle/snowmobile use and outdoor recreation; (3) National Historic Trails and cultural resources management; (4) management of wildlife habitat, including special status plant and animal species; (5) special management designations; and (6) travel management planning.

The Draft RMP/EIS included analysis of nine new areas proposed for consideration as Areas of Critical Environmental Concern (ACEC). The BLM found that these areas meet relevance and importance criteria as set forth in 43 CFR 1610.7–2, and the impacts of including these proposed ACECs were analyzed as part of the alternatives in the Draft RMP/EIS.

With Alternative D (BLM Preferred Alternative), the BLM proposes to establish the Bridger Butte ACEC (727 acres); Special status plant species ACEC (907 acres); and Cushion plant community ACEC (61 acres); and retain the Raymond Mountain ACEC (13,926 acres).

In addition, in Alternative D, the BLM analyzed the effects of opening 3,963 acres for consideration of future coal leasing. The proposed coal lease area is situated in T. 17 N., R. 117 W., Section 18, 20, 30, and 32; T. 16 N., R. 118 W., Section 2; 17 N., R. 118 W., Section 24.

Comments on the Draft RMP/EIS received from the public and internal BLM review were incorporated as appropriate into the proposed plan. After careful consideration of the comments received, adjustment and clarifications were made to Alternative D, BLM's Preferred Alternative. As modified, Alternative D is now presented as the Proposed Kemmerer RMP in the PRMP/FEIS. The Proposed Kemmerer RMP would provide comprehensive, long-range decisions for the use and management of resources in the planning area administered by the BLM and focus on the principles of multiple use and sustained yield.

Instructions for filing a protest with the Director of the BLM regarding the PRMP/FEIS may be found in the Dear Reader Letter of the Kemmerer PRMP/FEIS and at 43 CFR 1610.5–2. E-mailed and faxed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular or overnight mail postmarked by the close of the protest period. Under these conditions, the BLM will consider the e-mailed or faxed protest as an advance copy and it will receive full consideration. If you wish to provide the BLM with such advance notification, please direct faxed protests to the attention of the BLM protest coordinator at 202–452–5112, and e-mails to *Brenda_Hudgens-Williams@blm.gov.* All protests, including the follow-up letter (if e-mailing or faxing) must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section above. Before including your address, phone number, e-mail address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Martin G. Griffith,

Acting State Director.

[FR Doc. E8–19387 Filed 8–21–08; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

National Park Service

60-Day Notice of Intention To Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: Department of the Interior, National Park Service.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 and 5 CFR Part 1320, Reporting and Record Keeping Requirements, the National Park Service (NPS) invites public comments on a proposed new collection of information (1024-xxxx).

DATES: Public comments will be accepted on the proposed Information Collection Request (ICR) on or before October 21, 2008.

ADDRESSES: Send comments to: Margaret Littlejohn; Park Studies Unit, College of Natural Resources, University of Idaho; P.O. Box 441139, Moscow, Idaho 83844–1139; or via phone at 208/885–7863; or via fax at 208/885–4261; or via e-mail at *littlej@uidaho.edu.* Also, you may send comments to Leonard E. Stowe, NPS Information Collection Clearance Officer, 1849 C St., NW., (2605), Washington, DC 20240; or via e-mail at *leonard stowe@nps.gov.* All responses to this notice will be summarized and included in the request for the Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Dr. James Gramann, NPS Social Science Program, 1201 ''Eye'' St., Washington, DC 20005; or via phone at 202/513–7189; or via e-mail at *James_Gramann@partner.nps.gov* . You are entitled to a copy of the entire ICR package free of charge.

SUPPLEMENTARY INFORMATION:

Title: Programmatic Approval for the National Park Service Visitor Services Project

Bureau Form Number: None

OMB Number: To be requested.

Expiration Date: To be requested.

Type of Request: New collection.

Description of Need: The National Park Service (NPS) relies on accurate information concerning park visitors to inform planning and management aimed at better serving the visiting public. The NPS collects information on visitors' characteristics, opinions, preferences, and trip expenditures by means of visitor surveys, including those conducted by the NPS Visitor Services Project (VSP). Each year, the VSP completes up to 18 visitor surveys and focus groups in individual units of the National Park System. The NPS currently has a programmatic approval for NPS-sponsored public surveys (1024–0224). This programmatic approval has resulted in dramatic improvements in the agency's ability to conduct social science research in and around NPS units. The proposed VSP Programmatic Approval would extend these benefits by allowing this relatively homogeneous subset of information collections to go through its own review process. This will reduce the time that it takes for VSP information collections to be reviewed and fielded, benefiting parks that depend on VSPs to collect timely and accurate data from visitors for planning and management purposes.

The VSP conducts site-specific information collections, including in-depth visitor surveys and focus groups, at up to 18 parks per year. These studies

are similar in terms of the populations contacted, the types of questions asked, and the research methods employed. Due to these similarities, the NPS is proposing to the OMB an alternative approach to complying with the Paperwork Reduction Act by allowing individual VSP information collection requests to be submitted to OMB under the proposed Programmatic Approval. Implementation of this proposal will lead to less time involved in creating submissions for individual VSP collections and decreased review times for studies submitted under the Programmatic Approval. The obligation to respond is voluntary.

Automated data collection: This information will be collected via mail-back surveys or standard focus group protocols. No automated data collection will take place.

Description of respondents: A sample of visitors to parks and/or residents of communities near parks.

Estimated average number of respondents: The program does not identify the number of respondents because that number will differ in each information collection, depending on the purpose and design of the project.

Estimated average number of responses: The program does not identify the number of responses because that number will differ in each information collection. For most projects, respondents will be asked to respond only one time. In those cases, the number of responses will be the same as the number of respondents.

Estimated average burden hours per response: Completion times for individual visitor surveys conducted by the VSP average around 20 minutes per respondent. Average contact times are one minute per contact. Focus groups average two hours in length.

Frequency of Response: 1 time per respondent.

Estimated total annual reporting burden: The program identifies the requested total number of burden hours annually for all information collections to be 10,000 burden hours per year. The total annual burden per project for most studies conducted under the auspices of this program will be within the range of 100 to 900 burden hours.

Comments are invited on: (1) the practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden hour to respondents, including use of automated information techniques or other forms of information technology. Before including your address, phone number, e-mail address, or other personal identifying information in your comment—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: August 7, 2008.

Leonard E. Stowe,

NPS, Information Collection Clearance Officer.

[FR Doc. E8–19427 Filed 8–21–08; 8:45 am]

BILLING CODE 4312–52–M

DEPARTMENT OF THE INTERIOR

National Park Service

60-Day Notice of Intention To Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: Department of the Interior, National Park Service.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 and 5 CFR Part 1320, Reporting and Record Keeping Requirements, the National Park Service (NPS) invites public comments on a proposed new collection of information (1024–xxxx).

DATES: Public comments will be accepted on the proposed Information Collection Request (ICR) on or before October 21, 2008.

ADDRESSES: Send comments to: Tatjana Rosen, School of Forestry and Environmental Studies, Yale University, 205 Prospect Street, New Haven, CT 06511; or via e-mail at *Tatjana.Rosen@yale.edu*. Also, you may send comments to Leonard E. Stowe, NPS Information Collection Clearance Officer, 1849 C St., NW., (2605), Washington, DC 20240; or via e-mail at *leonard_stowe@nps.gov.* All responses to this notice will be summarized and included in the request for the Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

To request a draft of proposed collection of information contact: Tatjana Rosen, School of Forestry and Environmental Studies, Yale University, 205 Prospect Street, New Haven, CT 06511; or via e-mail at *Tatjana.Rosen@yale.edu.*

FOR FURTHER INFORMATION CONTACT: Dr. James Gramann, National Park Service Social Science Program, 1201 ''Eye'' St., Washington, DC 20005; or via phone at 202/513–7189; or via e-mail at *James_Gramann@partner.nps.gov*. You are entitled to a copy of the entire ICR package free of charge.

SUPPLEMENTARY INFORMATION: *Title:* Economic Study of Roadside Bear Viewing in Yellowstone National Park.

Bureau Form Number: None.

OMB Number: To be requested.

Expiration Date: To be requested.

Type of Request: New Collection.

Description of Need: Yellowstone National Park (YNP) now attempts to enhance opportunities for roadside bear viewing by leaving bears in proximity of park roads and devoting resources to managing ''bear jams'' (traffic jams created by visitors stopping to view the bears) and their associated challenges. Three questions arise with respect to this policy. First, what economic value does the opportunity to view bears near roads in YNP have to the visitors themselves; second, what are visitors' perceptions about the current roadside bear management policy; and third, what impact does the policy to allow bears to remain in roadside locations have on YNP visitation rates and on visitors' broader views of bears, other wildlife, and other natural resources.

To explore these questions, YNP is planning to use a mail-back questionnaire designed to systematically collect data from visitors in the following areas: Visit and individual characteristics, importance of different natural resources to the trip, acceptability of different wildlife management practices for roadside bear viewing, effects of management policy changes on the decision to return to the park (including regional economic impact) and perspectives on roadside bear viewing. The information acquired will help determine the effectiveness of current bear roadside management practices and—if the results so show—provide a credible basis to seek additional funds to manage roadside bears. The Bear Management Office in YNP has collected data on ''bear jams'' reported in the park since 2000, including the number of personnel hours spent by park staff in order to keep bear jams safe and visitors satisfied. Currently there are more ''bear jams'' than park rangers to manage them and several visitors and ''bear enthusiasts'' have expressed some level of concern about that situation.

The results of the survey will help define the costs and benefits associated with the current roadside bear management policy in YNP. In addition, it will provide park managers and others with important, accurate information about the YNP visitor population in general, as well as visitor and trip

characteristics of those who specifically view bears on roadsides in the park. The importance of visitation specifically tied to roadside bear viewing in the park will be examined. The NPS's goal in conducting this survey is to evaluate the importance and economic effects of roadside bear viewing. The obligation to respond is voluntary.

Automated data collection: This information will be collected via mail-back surveys no automated data collection will take place.

Description of respondents: Visitors to Yellowstone National Park.

Estimated average number of respondents: 1000 (800 respondents and 200 non-respondents).

Estimated average number of responses: 1000 (800 responses and 200 non-responses).

Estimated average burden hours per response: 21 minutes per respondent and 1 minute per non-respondent.

Frequency of response: 1 time per respondent and non-respondent.

Estimated annual reporting burden: 283 hours.

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: August 7, 2008.

Leonard E. Stowe,

NPS, Information Collection Clearance Officer.

[FR Doc. E8–19429 Filed 8–21–08; 8:45 am]

BILLING CODE 4312–52–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–487 (Remand)]

In the Matter of Certain Agricultural Vehicles and Components Thereof; Notice of Commission Determination To Reverse a Remand Initial Determination of the Administrative Law Judge That Section 337 Has Been Violated; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to reverse the presiding administrative law judge's finding of violation of section 337 of the Tariff Act, as amended, on remand and has terminated the investigation.

FOR FURTHER INFORMATION CONTACT: Jonathan J. Engler, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3112. The public version of the ALJ's final ID and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS–ON–LINE) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on February 13, 2003, based on a complaint filed by Deere & Company (''Deere'') of Moline, Illinois. 68 FR 7388 (February 13, 2003). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, sale for importation, and sale within the United States after importation of certain agricultural vehicles and components thereof by reason of infringement and dilution of U.S. Registered Trademarks Nos. 1,254,339; 1,502,576; 1,503,576, and 91,860.

Twenty-four respondents were named in the Commission's notice of investigation. Most of the respondents were terminated from the investigation on the basis of consent orders, or found in default. The remaining respondents, Erntetechnik Franz Becker; Sunova Implement Company; Bourdeau Bros., Inc. and OK Enterprises (collectively, ''the Bourdeau respondents''); Fitzpatrick Farms; Stanley Farms; J&T Farms; and Co-Ag LLC (collectively, ''the Fitzpatrick Farms respondents''); and Agrideal participated in the investigation. On January 13, 2004, the ALJ issued his final initial determination (''ID'') finding a violation of section 337. He also recommended the issuance of remedial orders. The Bourdeau respondents and Fitzpatrick Farms respondents petitioned for review of the ID.

On March 30, 2004, the Commission determined not to review the ID. The Commission then issued a general exclusion order directed to Deere European-version self propelled forage harvesters, two limited exclusion orders directed to Deere European-version telehandlers, and various cease and desist orders, on May 14, 2004.

The Bourdeau respondents appealed the Commission's final determination to the U.S. Court of Appeals for the Federal Circuit (the ''Federal Circuit''). On March 30, 2006, the Federal Circuit vacated and remanded the Commission's final determination as it related to Deere European-version self-propelled forage harvesters (''EVSPFHs''). *Bourdeau Bros.* v. *International Trade Commission*, 444 F.3d 1317 (Fed. Cir. 2006).

On June 20, 2006, the Commission rescinded the general exclusion order and certain cease and desist orders, and remanded the investigation to the presiding ALJ for proceedings consistent with the Federal Circuit's decision in *Bourdeau.* On August 18, 2006, the ALJ issued Order No. 55, denying complainant's and respondents' motions for summary determination. The ALJ issued his final ID on remand (''Remand ID'') on December 20, 2006. He found that Deere did not authorize the sale of Deere European-version self-propelled forage harvesters in the United States and that all or substantially all of the Deere self-propelled forage harvesters sold in the United States were North American versions. In further briefing before the Commission, the respondents claimed error.

On February 20, 2007, the Commission determined to review in part Order No. 55 and the Remand ID. The Commission requested briefing by the parties (1) On the standard for authorization that was applied in Order No. 55 and how that standard was applied in light of the burden of proof;

(2) on the issue of Deere's alleged financing of certain EVSPFHs; (3) with respect to the ALJ's application of the ''all or substantially all'' standard, including a statement of the type and number of sales relied on and the basis for reliance on those sales, especially the basis for including used sales of North American-version harvesters in the assessment of whether that standard has been met by Deere; and (4) on whether all or substantially all of Deere's sales of SPFHs were of North American versions of these machines.

On March 13, 2008, the Commission asked the parties to discuss (1) The total quantity of new and used EVSPFHs sold by John Deere's official European dealers to the United States from 1997 through 2002, including (a) all European dealer sales for importation to the United States for which there is documentary evidence in the existing record and (b) an estimate of the total quantum of additional European dealer sales for importation to the United States for which there may not be documentary evidence on this record; (2) an exclusively legal discussion of the relevance of the agency doctrines of actual and apparent authority in the context of gray market sales in the United States; and (3) whether, if the Commission were to take into account only sales of gray market EVSPFHs by U.S. dealers (i.e. sales within the United States after importation), and not sales for importation of gray market goods by John Deere's European dealers, it would in effect improperly limit the scope of the unlawful activities that it is required to consider under the statute, which includes within the Commission's jurisdiction ''the sale for importation'' as well as ''the sale within the United States after importation'' of articles that infringe a valid United States trademark. 19 U.S.C. Section 1337(a)(1)(C).

Written submissions were received by the parties on April 15 and April 24, 2008. On April 30, the parties each filed reply submissions.

Having considered the record and briefing in this investigation, the Commission has determined to reverse the ALJ's finding of violation. A Commission Opinion in support of its determinations will follow shortly.

The authority for this notice is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.45(c) of the Commission's Rules of Practice and Procedure (19 CFR 210.45(c)).

By order of the Commission.

Issued: August 12, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–19571 Filed 8–21–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decrees Under the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that two Consent Decrees in *United States of America* v. *M.A. Hanna Plastics, Inc., et al.*, Civil Action No. 06–409 GMS, have been lodged with the United States District Court for the District of Delaware. The United States lodged a consent decree with defendant Wilmington Economic Development Corporation \ (''WEDCO'') on August 8, 2008, and lodged a consent decree with defendant M.A. Hanna Plastics Group \''Hanna'') on August 14, 2008.

The two consent decrees will resolve the liability of the two remaining defendants in this cost recovery action under Section 107 of the Comprehensive Environmental Response, Compensation and Liability Act \ (''CERCLA''), 42 U.S.C. 9607 in connection with the 12th Street Dump Site in Wilmington, Delaware \(''Site''). On June 28, 2006, the United States filed a Complaint against four defendants who currently or previously owned or operated property at the Site. The United States previously settled with two of the named defendants.

The two consent decrees now being proposed will resolve the United States' filed claims against the two remaining defendants, Hanna and WEDCO, as set forth in the consent decrees. Hanna will reimburse the United States $3,597,877.20 and will receive a covenant not to sue for past costs. WEDCO will reimburse the United States $120,000 in past costs and will agree to sell its parcel and provide the United States with the higher of either 50% of the net proceeds or $40,000.00. WEDCO will also receive a covenant not to sue for past costs.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to these proposed Consent Decrees. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, Attention: Nancy Flickinger (EES), and should refer to *United States of America* v. *M.A. Hanna Plastics, Inc., et al.* , Civil Action No. 06–409 GMS, DOJ # 90–11–3–08301.

The proposed Consent Decree may be examined at the Office of the United States Attorney for the District of Delaware, Nemours Building, P.O. Box 2046, Wilmington, DE 19801. During the public comment period, the consent decree may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html*. A copy of the proposed Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $ $7.00 for the consent decree with WEDCO, and/or $5.25 for the consent decree with M.A. Hanna (25 cents per page reproduction cost for a full copy) payable to the U.S. Treasury.

Maureen M. Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–19447 Filed 8–21–08; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response Compensation and Liability Act

Pursuant to 28 CFR 50.7 notice is hereby given that on August 14, 2008, a proposed Consent Decree in the case *United States* v. *William J. Roper, Sr., et al.*, Civil Action No. 3:00cv472–GCM, was lodged with the United States District Court for the Western District of North Carolina.

In this action, under Section 107(a)(1) and (2) of CERCLA, 42 U.S.C. 9607(a)(1) and (2), the United States sought recovery of response costs to remedy conditions in connection with the release or threatened release of hazardous substances into the environment at the North Belmont PCE Site (''the Site''), located in Belmont, Gaston County, North Carolina. A portion of the Site is comprised of the Roper Shopping Center upon which the United States had placed a Superfund Lien. The Complaint also included an *in rem* action under Section 107(l) of

CERCLA, 42 U.S.C. 9607(l), to enforce this lien.

The proposed consent decree requires Defendants to exercise best efforts to sell the Roper Shopping Center which is currently valued at about $303,000. The United States will receive 75 percent of the sale proceeds in partial reimbursement of outstanding response costs.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and mailed either electronically to *pubcomment-ees.enrd@usdoj.gov* or in hard copy to the United States Department of Justice, P.O. Box 7611, Ben Franklin Station, Washington, DC 20044–7611 and should refer to *United States* v. *William J. Roper, Sr., et al.*, D.J. Ref. 90–11–3–07246.

The proposed Consent Decree may be examined at the U.S. Environmental Protection Agency, Region IV, 61 Forsythe Street, Atlanta, Georgia 30303. During the public comment period, the Consent Decree, may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.*

A copy of the Consent Decree may also be obtained by mail from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy of the Consent Decree from the Consent Decree Library, please enclose a check in the amount of $9.75 (25 cents per page reproduction cost × 39 pages) payable to the U.S. Treasury.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section.

[FR Doc. E8–19468 Filed 8–21–08; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Judgment Pursuant to Resource Recovery and Conservation Act

Notice is hereby given that on August 15, 2008, a proposed Consent Judgment in *United States* v. *175 Inwood Associates, et al.* , Civil Action No. CV–96–1471, was lodged with the United States District Court for the Eastern District of New York.

The proposed Consent Judgment will resolve the United States' claims under Sections 104, 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9604, 9606 and 9607, as amended (''CERCLA''), on behalf of the U.S. Environmental Protection Agency (''EPA'') against 175 Inwood Associates, Abraham Woldiger, Abraham Taub, and Peter Hoffman (collectively ''defendants'') regarding the Rockaway Metal Products Superfund Site in Inwood, New York. By Memorandum and Order dated August 6, 2004, the United States District Court for the Eastern District of New York Court held that defendants were responsible for the EPA's past response costs and were liable for civil penalties under CERCLA Section 104 and Section 106 for violations of two EPA orders and failures to respond to EPA requests for information.

The Consent Judgment requires defendant Peter Hoffman to pay to the United States the total sum of $350,000, which includes EPA's past response costs in the amount of $150,000 and civil penalties in the amount of $200,000, and requires defendants Abraham Woldiger and Abraham Taub to each pay to the United States civil penalties in the amount of $25,000. The civil penalties are for defendants' partial violations of the EPA orders and EPA requests for information. With respect to defendants Woldiger and Hoffman, the settlement amount was calculated after conducting an ability-to-pay analysis.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the Consent Judgment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *175 Inwood Associates, et al.*, Civil Action No. CV–96–1471, D.J. Ref. No. 90–11–2–1079.

The proposed Consent Judgment may be examined at the Office of the United States Attorney, Eastern District of New York, 271 Cadman Plaza East, 7th Fl., Brooklyn, New York 11201, and at the United States Environmental Protection Agency, Region II, 290 Broadway, New York, New York 10007–1866. During the public comment period, the proposed Consent Judgment may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed Consent Judgment may be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $5.25 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–19418 Filed 8–21–08; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Clean Diesel V

Correction

In notice document E8–17042 appearing on page 43952 in the issue of Tuesday, July 29, 2008, make the following correction:

On page 43952, in the first column, in the first paragraph, in the fifth line from the bottom, ''EASF'' should read ''BASF''.

[FR Doc. Z8–17042 Filed 8–21–08; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Advisory Committee on Construction Safety and Health (ACCSH); Notice of Renewal of Charter

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of Renewal of ACCSH Charter.

SUMMARY: In accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C., App. 2), and its implementing regulations (41 CFR 102–3, Federal Advisory Committee Management), the Secretary of Labor has determined that the renewal of the Charter for the Advisory Committee on Construction

Safety and Health (ACCSH) is necessary and in the public interest. Accordingly, the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) has renewed the ACCSH Charter with several minor revisions. The revisions relate to procedural matters which do not substantively affect the objectives or activities of the ACCSH Committee. The ACCSH Charter will expire on May 6, 2010.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Hajdusiewicz, Office of Construction Service, Directorate of Construction, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3468, 200 Constitution Avenue, NW., Washington, DC 20210; Telephone: (202) 693–2020 or Facsimile: (202) 693–1689.

SUPPLEMENTARY INFORMATION:

I. Background

The Committee will advise the Assistant Secretary of Labor for Occupational Safety and Health in the formulation of construction safety and health standards under the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*), commonly known as the Construction Safety Act (CSA), and the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*). The ACCSH also provides advice on the administration of the safety and health provisions of the CSA (29 CFR 1912.5(c)).

Under OSHA regulations (29 CFR 1912.3), the ACCSH is composed of 15 members appointed by the Assistant Secretary as follows: One member who is a designee of the Secretary of Health and Human Services; five members who are qualified by experience and affiliation to represent the viewpoint of employers involved in construction; five members, similarly qualified, to represent the viewpoint of the employees involved in construction, two members who are representatives of State safety and health agencies; and two members who are qualified by knowledge and experience to represent the general public and to make a useful contribution to the work of the Committee. One of the members is appointed to serve as the Committee chair. Members generally serve two-year staggered terms except for the designee of the Secretary of Health and Human Services who has no fixed term. Members may be appointed to serve successive terms or may be removed at any time and replaced. If otherwise qualified, a member may continue to serve after his or her term expires, until successors are appointed.

The ACCSH charter is required to be renewed every two years. The current charter was to have expired on July 3, 2008. In light of the Committee's past contribution toward OSHA's construction safety and health mission, OSHA has determined that renewal of the charter for another two years is necessary and in the public interest. In addition to the renewal, OSHA has amended the charter to address procedural matters in the following sections: the Objectives and Scope of Activity section was amended to include references to the Federal Advisory Committee Act to be consistent with the Department's procedures; the Membership section was amended to more accurately reflect Committee members' terms of service, the Estimated Annual Operating Costs in Dollars and Staff Years section was amended to reflect increases in the Committee's annual budget ($152,000 to $180,000) to account for increased costs for travel, logistical and conference support for the Committee and its workgroup meetings; and the Meetings section was amended to reflect that the Committee is generally expected to meet between two and four times per year.

II. Authority and Signature

Edwin G. Foulke, Jr., Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is granted by section 7 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 656), section 107 of the Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 3701 *et seq.*), 29 CFR 1911 and 1912, and Secretary of Labor's Order No. 5–2007 (72 FR 31159).

Signed at Washington, DC on August 14th, 2008.

Edwin G. Foulke, Jr.

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. E8–19444 Filed 8–21–08; 8:45 am]

BILLING CODE 4510–26–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 2006–5 CRB DD 2002–2004]

Distribution of the 2002, 2003, and 2004 Digital Audio Recording Technology Royalty Funds

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Notice announcing commencement of proceeding with request for Petitions to Participate.

SUMMARY: The Copyright Royalty Judges are announcing the commencement of the proceeding to determine the distribution of the digital audio recording technology royalty fees in the 2002, 2003, and 2004 Musical Works Funds. The Judges are also announcing the date by which a party who wishes to participate in this proceeding must file its Petition to Participate and the accompanying $150 filing fee.

DATES: Petitions to Participate and the filing fee are due no later than September 22, 2008.

ADDRESSES: An original, five copies, and an electronic copy in Portable Document Format (PDF) on a CD of the Petition to Participate, along with the $150 filing fee, may be delivered to the Copyright Royalty Board by either mail or hand delivery. Petitions to Participate and the $150 filing fee may not be delivered by an overnight delivery service other than the U.S. Postal Service Express Mail. If by mail (including overnight delivery), Petitions to Participate, along with the $150 filing fee, must be addressed to: Copyright Royalty Board, P.O. 70977, Washington, DC 20024–0977. If hand delivered by a private party, Petitions to Participate, along with the $150 filing fee, must be brought to the Library of Congress, James Madison Memorial Building, LM–401, 101 Independence Avenue, SE., Washington, DC 20559–6000. If delivered by a commercial courier, Petitions to Participate, along with the $150 filing fee, must be delivered to the Congressional Courier Acceptance Site, located at 2nd and D Street, NE., Washington, DC. The envelope must be addressed to: Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue, SE., Washington, DC 20559–6000.

FOR FURTHER INFORMATION CONTACT: LaKeshia Brent, CRB Program Specialist. Telephone: (202) 707–7658. Telefax: (202) 252–3423 or e-mail at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Audio Home Recording Act of 1992 (the ''AHRA''), Public Law 102–563, requires manufacturers and importers to pay royalties on digital audio recording devices and media that are distributed in the United States. 17 U.S.C. 1003. These royalties are deposited with the Copyright Office for further distribution among interested copyright parties by the Copyright Royalty Judges (''Judges''), provided that the interested copyright parties file a claim with the Copyright Royalty Board

each year during the months of January and February. 17 U.S.C. 1005, 1007.

The AHRA provides that the royalties are divided between two funds: the Sound Recordings Fund and the Musical Works Fund. The Sound Recordings Fund receives 66⅔% of the royalties and the Musical Works Fund receives the remaining 33⅓%. These fees are allocated further to specific subfunds.

The Sound Recordings Fund consists of four subfunds: the Featured Artists Subfund, the Copyright Owners Subfund, the Nonfeatured Musicians Subfund, and the Nonfeatured Vocalists Subfund. The royalty fees allocated to the Sound Recordings Funds are divided among these four subfunds according to the percentages set out in section 1006 of the Copyright Act. 17 U.S.C. 1006(b)(1). Similarly, the statute prescribes that the royalty fees allocated to the Musical Works Fund be divided equally between two subfunds, the Publishers Subfund and the Writers Subfund. 17 U.S.C. 1006(b)(2).

Distribution of these fees may occur in one of two ways. The interested copyright parties within each subfund may either negotiate the terms of a settlement as to the division of royalty funds,[1] or the Copyright Royalty Judges may conduct a proceeding to determine the distribution of the royalties that remain in controversy in each subfund. *See* 17 U.S.C. 1006(c).

On May 19, 2006, the Judges received a motion filed jointly by Broadcast Music, Inc., the American Society of Composers, Authors and Publishers, SESAC, Inc., and the Harry Fox Agency (hereinafter ''the Settling Parties'') asking the Judges to authorize a partial distribution of 95% of the 2002, 2003, and 2004 digital audio recording technology (''DART'') Musical Works Funds. The Settling Parties sought the distribution under 17 U.S.C. 801(b)(3)(A), which provides that royalty fees not subject to controversy may be distributed by the Judges. Subsequently, on September 27, 2006, the Judges held a hearing on the motion; and after considering the views of the claimants participating in the hearing, including an objection to the motion by one claimant, the Judges granted the motion, finding that retention of 5% of the 2002, 2003, and 2004 DART Musical Works Funds would be sufficient to resolve any potential controversies as to the distribution of royalties. *See* Order in Docket No. 2006–5 CRB DD 2002–2004 (October 2, 2006). The Judges also determined that it would begin a proceeding to resolve any existing controversies as to the remaining 5% of the 2002, 2003, and 2004 DART Musical Works Funds.[2] *Id.* Today's notice commences that proceeding.

Commencement of Proceeding

Consistent with 17 U.S.C. 804(b)(8), the Judges determine that a controversy exists as to the distribution of the 2002, 2003, and 2004 DART Musical Works Fund. We reach this determination, in this instance, for two reasons. First, an objection to the motion for partial distribution was raised by a claimant who participated in the September 27, 2006, hearing. Second, to date we have not received notification that any settlements have been reached for any of these years, nor have we received motions for final distribution.

The Judges are consolidating the consideration of the distribution of the 2002, 2003, and 2004 DART Musical Works Funds into a single proceeding because the issues regarding the distribution of the royalty fees are similar, if not the same, for each year. Moreover, due to the relatively low amount of funds for each year, consolidation provides a cost savings to the parties and promotes administrative efficiencies.

Petitions To Participate

Petitions to Participate must provide all of the information required by 37 CFR 351.1(b)(2). Participants also must identify by year each subfund in the Musical Works Fund to which they are asserting a claim to royalties. Petitions to Participate submitted by interested parties whose claims do not exceed $1,000[3] must contain a statement that the party will not seek a distribution of more than $1,000. No filing fee is required for these parties. Interested parties with claims exceeding one thousand dollars ($1,000), however, must submit a filing fee of one hundred and fifty dollars ($150) with their Petition to Participate or it will be rejected. Cash will not be accepted; therefore, parties must pay the filing fee with a check or money order made payable to the ''Copyright Royalty Board.'' If a check is returned for lack of sufficient funds, the corresponding Petition to Participate will be dismissed.

Further procedural matters, including scheduling, will be addressed after Petitions to Participate have been received.

In accordance with 37 CFR 350.2 (Representation), only attorneys who are members of the bar in one or more states and in good standing will be allowed to represent parties before the Copyright Royalty Judges, unless the party is an individual who represents herself or himself.

Dated: August 18, 2008.

James Scott Sledge,

Chief United States Copyright Royalty Judge.

[FR Doc. E8–19570 Filed 8–21–08; 8:45 am]

BILLING CODE 1410–72–P

[1] For each of the claim years 2002, 2003, and 2004, the interested copyright parties to the royalty fees in the Sound Recordings Funds have negotiated a universal settlement agreement among themselves as to the proportionate share that each party receives from the subfunds; consequently, these funds have been distributed.

[2] On July 1, 2008, the Settling Parties filed a motion requesting commencement of the proceeding mentioned in the October 2, 2006, order.

[3] The Copyright Royalty Judge Program Technical Corrections Act, Public Law 109–303, changed the amount from $10,000 to $1,000.

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency has submitted to OMB for approval the information collection described in this notice. The public is invited to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted to OMB at the address below on or before September 22, 2008 to be assured of consideration.

ADDRESSES: Send comments to Desk Officer for NARA, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5167.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collection and supporting statement should be directed to Tamee Fechhelm at telephone number 301–837–1694 or fax number 301–713–7409.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Public Law 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. NARA published a notice of proposed collection for this information collection on June 9, 2008 (73 FR 32604 and 32605). No comments were received. NARA has submitted the described information collection to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of information technology; and (e) whether small businesses are affected by this collection. In this notice, NARA is soliciting comments concerning the following information collection:

1. *Title:* Researcher Application.

OMB number: 3095–0016.

Agency form number: NA Form 14003.

Type of review: Regular.

Affected public: Individuals or households, business or other for-profit, not-for-profit institutions, Federal, State, Local or Tribal Government.

Estimated number of respondents: 18,487.

Estimated time per response: 8 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 2,465 hours.

Abstract: The information collection is prescribed by 36 CFR 1254.8. The collection is an application for a research card. Respondents are individuals who wish to use original archival records in a NARA facility. NARA uses the information to screen individuals, to identify which types of records they should use, and to allow further contact.

Dated: August 18, 2008.

Martha Morphy,

Assistant Archivist for Information Services.

[FR Doc. E8–19520 Filed 8–21–08; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by September 22, 2008. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 292–7405.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Public Law 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Permit Application No. 2009–010

The applications received are as follows:

1. *Applicant:* Lisa K. Blatt, 1695 North Point Street, #204, San Francisco, CA 94123.

Activity for Which Permit Is Requested

Enter Antarctic Specially Protected Areas. The applicant is a member of the Antarctic Artists and Writers Program and plans to enter ASPA 155—Cape Evans (Scott's Hut), ASPA 157—Backdoor Bay, Cape Royds (Shackelton's Hut), and ASPA 158—Hut Point (Discovery Hut). The applicant plans to photograph and document the historical aspect of man's interaction with his environment in the historic huts and allow broader comparisons to the current interactions at McMurdo Station, and science camps.

Location

ASPA 155—Cape Evans (Scott's Hut), ASPA 157—Backdoor Bay, Cape Royds (Shackelton's Hut), and ASPA 158—Hut Point (Discovery Hut).

Dates

October 2, 2008 to February 28, 2009.

Permit Application No. 2009–016

2. *Applicant:* Hubertus Staudigel, Scripps Institution of Oceanography, UCSD–0225, La Jolla, CA 92093–0225.

Activity for Which Permit Is Requested

Enter Antarctic Specially Protected Area. The applicant plans to enter ASPA 130—Tramway Ridge, Mt. Erebus as it offers a unique opportunity to study microbial glass alteration because it is minimally affected by any major disturbance from people or multi-cellular life and it provides an extremely attractive natural laboratory that simulates microbe-rock interactions in an organics-poor environment. In such an environment, it is most likely to find truly chemo-autotrophic metabolisms. As such, it may be considered a close analog to microbial habitats of the early earth. In addition, Tramway Ridge is exposed to some unique extreme environmental conditions which offers much potential for identifying novel and specially adapted microbes.

Location

ASPA 130—Tramway Ridge, Mt. Erebus.

Dates

December 1, 2008 to December 31, 2008.

Permit Application No. 2009–017

3. *Applicant:* Cheryl E. Leonard, 2352 Fulton Street, San Franciso CA 94118.

Activity for Which Permit is Requested

Take. The applicant is a member of the Antarctic Artists and Writers program and plans to salvage bones from deceased Adelie, Chinstrap and Gentoo penguins. The bones, along with rocks, ice, fossils, feathers, shells, and water will be played literally as musical instruments as part of the project, ''Antarctica: Hidden Musical Worlds''. These natural instruments will be the primary source of sounds for the musical pieces created for this project, although some works will also incorporate field recordings of birds, animals, ice and water. The project will culminate in a series of live concerts at science museums, aquariums, and concert halls throughout the U.S. and will be released on a DVD with international distribution.

Location

Palmer Station vicinity, Anvers Island.

Dates

November 1, 2008 to September 30, 2009.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. E8–19456 Filed 8–21–08; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by September 22, 2008. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 292–7405.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Permit Application No. 2009–018

The applications received are as follows:

1. *Applicant:* Mahlon C. Kennicutt, II, Director, Sustainable Development, Team Leader, Sustainable Coastal Margins Program, Texas A&M University, 1112, College Station, TX 77843–1112.

Activity for Which Permit Is Requested

Enter Antarctic Specially Protected Areas. The applicant plans to enter ASPA 116—New College Valley, Cape Bird, ASPA 122—Arrival Heights, Ross Island, and ASPA 158—Hut Point, Ross Island. These sites are specifically targeted because of the nature of their geology, climatic influences and topography. The applicant plans on sampling one site as a reference control area for the study of the temporal and spatial scales of various types of disturbances in and around McMurdo Station. In addition, a reconnaissance flight from Cape Roberts to Cape Chocolate to identify an additional reference control site will be made. The other sites, Arrival Heights (ASPA 122) and Hut Point (ASPA 158) have been sampled in past field seasons and are slated to be sampled as part of the ongoing environmental monitoring program.

Location

ASPA 116—New College Valley, Cape Bird, ASPA 122—Arrival Heights, Ross Island, and ASPA 158—Hut Point, Ross Island.

Dates

November 17, 2008 to December 31, 2008.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. E8–19464 Filed 8–21–08; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide: Granting Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Granting of Request To Extend the Comment Period of Draft Regulatory Guide (DG)–1200, ''An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities.''

FOR FURTHER INFORMATION CONTACT: Mary Drouin, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: (301) 415–6675 or e-mail to *Mary.Drouin@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) issued for public comment DG–1200, which was published in the **Federal Register**, 73 FR 35170, on June 20, 2008. DG–1200 is proposed Revision 2 of Regulatory Guide 1.200 in the agency's Regulatory Guide Series. This series has been developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

II. Further Information

The NRC staff requested receipt of comments on DG–1200 by August 25, 2008, (including any implementation schedule) and its associated regulatory analysis or value/impact statement. By this action, the NRC staff is extending the comment period until September 24, 2008. Comments received after September 24, 2008, would be considered if practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

III. Request To Extend the Comment Period

Basis for the Request

The NRC received the following extension request:

''There is currently work underway by the American Society of Mechanical Engineers (ASME) to address many fundamental issues with the Joint ASME/American Nuclear Society (ANS) PRA [probabilistic risk assessment] Standard, many of which are items likely identified in the current RG revision. These changes are identified as Addendum A to the ASME/ANS Joint PRA Standard.'' ''ASME is currently balloting these changes for approval, with a closure of the ballot in late August 2008. Once balloted and approved, these changes to the Joint Standard will be made available to the general public. Availability of such information will be important for the public to make an informed review of the draft RG 1.200, Revision 2. As a result of this schedule mismatch, the PWROG [pressurized water reactor owners' group] requests that the review period for the draft RG 1.200, Revision 2 be extended to allow the industry to integrate the findings and conclusions of the ASME/ANS Joint PRA Standard revisions in preparing an informed review. The

PWROG views changes in Addendum A substantial enough to warrant an extension of the public review period. Accordingly, we request a 60-day extension to the current review period.''

Response to Request

The request for an extension to the comment period is approved for 30 days.

The staff understands that ASME/ANS is working on an initial addendum (i.e., Addendum A) to Revision 1 of the ASME/ANS PRA Standard (RA–S–2008). However, at this time, Addendum A has not been approved by ASME/ANS, and consequently is not available to the public. Since the ASME/ANS ballot period has not closed, it is not known if there will be sufficient positive ballots approving Addendum A. Consequently, it is uncertain if and when ASME/ANS will issue Addendum A, and therefore, be available to the public. A 60-day extension to the public comment period for DG 1200 will impact the December 2008 publication date of Revision 2 of RG 1.200. With the uncertainty associated with the issuance of Addendum A of the ASME/ANS PRA standard, the staff does not support an extension of the comment period to DG 1200 that would impact the schedule for publishing Revision 2 to RG 1.200. However, the staff agrees with the PWROG with regard to the importance of Addendum A. The staff understands from ASME that the ballot closes September 12, 2008, at which time the status of Addendum A will be known. A 30-day extension to the comment period of DG 1200 will enable the staff the meet the publication schedule of December 2008 for Revision 2 to RG 1.200. Therefore, the staff is approving a 30-day extension to the public comment period, with the public comment period to end on September 24, 2008. Further, at that time, the status of Addendum A of the ASME/ANS PRA Standard will be known, and dependent on the content of Addendum A and the schedule for issuance, the staff may revisit the schedule for publishing Revision 2 of RG 1.200.

Requests for technical information about DG–1200 may be directed to the NRC contact, Mary Drouin at (301) 415–6675 or e-mail to *Mary.Drouin@nrc.gov.*

Electronic copies of DG–1200 are available through the NRC's public Web site under Draft Regulatory Guides in the ''Regulatory Guides'' collection of the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/doc-collections/*. Electronic copies are also available in ADAMS (*http://www.nrc.gov/reading-rm/adams.html*), under Accession No. ML081200566.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR), which is located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555–0001. The PDR can also be reached by telephone at (301) 415–4737 or (800) 397–4205, by fax at (301) 415–3548, and by e-mail to *pdr.resource@nrc.gov.*

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 19th day of August 2008.

For the Nuclear Regulatory Commission.

Stephen C. O'Connor,

Acting Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. E8–19635 Filed 8–21–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Office of New Reactors; Interim Staff Guidance on Assessment of Normal and Extreme Winter Precipitation Loads on the Roofs of Seismic Category I Structures

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Solicitation of public comment.

SUMMARY: The NRC is soliciting public comment on its Proposed Interim Staff Guidance (ISG) DC/COL–ISG–07 (ADAMS Accession No. ML081980084). The purpose of this ISG is to clarify the NRC position on identifying winter precipitation events as site characteristics and site parameters for determining normal and extreme winter precipitation loads on the roofs of Seismic Category I structures. This ISG revises the previously issued staff guidance in March 2007 in the Standard Review Plan (SRP) NUREG–0080, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants.'' The NRC staff issues DC/COL–ISGs to facilitate timely implementation of the current staff guidance and to facilitate activities associated with review of applications for design certifications (DCs) and combined licenses (COLs) by the Office of New Reactors. The NRC staff will also incorporate the approved DC/COL–ISG–007 into the next revision of the SRP and related guidance documents.

DATES: Comments must be filed no later than 30 days from the date of publication of this notice in the **Federal Register**. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Comments may be submitted to: Chief, Rulemaking, Directives and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Comments should be delivered to: 11545 Rockville Pike, Rockville, Maryland, Room T–6D59, between 7:30 a.m. and 4:15 p.m. on Federal workdays. Persons may also provide comments via e-mail at *charles.cox@nrc.gov.* The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC Public Document Room reference staff at 1–800–397–4209, 301–415–4737, or by e-mail at *pdr.resource@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Charles R. Cox, Siting and Accident Consequence Branch, Division of Siting and Environmental Reviews, Office of the New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–2003 or e-mail at *charles.cox@nrc.gov.*

SUPPLEMENTARY INFORMATION: The agency posts its issued staff guidance in the agency external Web page (*http://www.nrc.gov/reading-rm/doc-collections/isg/*).

The NRC staff is issuing this notice to solicit public comments on the proposed DC/COL–ISG–007. After the NRC staff considers any public comments, it will make a determination regarding the proposed DC/COL–ISG–007.

Dated at Rockville, Maryland, the 15th day of August 2008.

For the Nuclear Regulatory Commission.

Nanette Gilles,

Acting Branch Chief Rulemaking, Guidance and Advanced Reactors Branch, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. E8–19554 Filed 8–21–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on September 4–6, 2008, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Monday, October 22, 2007 (72 FR 59574).

Thursday, September 4, 2008, Conference Room T–2b3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: License Renewal Application and Final SER for the Wolf Creek Generating Station, Unit 1 (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and Wolf Creek Nuclear Operating Corporation regarding the license renewal application for the Wolf Creek Generating Station, Unit 1, and the associated NRC staff's final Safety Evaluation Report (SER).

10:45 a.m.–12:15 p.m.: Draft Final Revision 1 to Regulatory Guide 1.131, ''Quantification of Safety-Related Cables and Field Splices for Nuclear Power Plants'' (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the draft final revision 1 to Regulatory Guide 1.131 and the NRC staff's resolution of public comments.

1:15 p.m.–3:15 p.m.: TRACE Computer Code Peer Review (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the findings of the Peer-Review Panel for the TRACE computer code and the staff's plans to address the Panel's findings.

3:30 p.m.–4:30 p.m.: Anticipated Advanced Reactor Research Needs (Open)—The Committee will discuss the anticipated advanced reactor research needs and related matters.

4:30 p.m.–7 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

Friday, September 5, 2008, Conference Room T–2b3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10 a.m.: Quality Assessment of Selected Research Projects (Open)—The Committee will hear a report by and hold discussions with the ACRS Panels which performed the quality assessment of the NRC research projects on: FRAPCON/FRAPTRAN Code work at the Pacific Northwest National Laboratory (PNNL), and NUREG/CR–6943, ''A Study of Remote Visual Methods to Detect Cracking in Reactor Components.''

10:15 a.m.–11:15 a.m.: Future Activities/Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the full Committee during future ACRS meetings and matters related to the conduct of ACRS business, including anticipated workload and member assignments.

11:15 a.m.–11:30 a.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

2 p.m.–7 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports.

Saturday, September 6, 2008, Conference Room T–2b3, Two White Flint North, Rockville, Maryland

8:30 a.m.–12 p.m.: Preparation of ACRS Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

12 p.m.–12:30 p.m.: Miscellaneous (Open)—The Committee will discuss matters related to the conduct of Committee activities and matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 26, 2007 (72 FR 54695). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Electronic recordings will be permitted only during the open portions of the meeting. Persons desiring to make oral statements should notify the Cognizant ACRS staff named below five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Cognizant ACRS staff prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

In accordance with Subsection 10(d) Public Law 92–463, I have determined that it may be necessary to close portions of this meeting noted above to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy pursuant to 5 U.S.C. 552b(c)(2) and (6).

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, as well as the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting Mr. Girija Shukla, Cognizant ACRS staff (301–415–6855), between 7:30 a.m. and 4 p.m., (ET). ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/ACRS/.*

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service for observing ACRS meetings should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m., (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the

equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated: August 18, 2008.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. E8–19485 Filed 8–21–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[EA–08–212]

In the Matter of; All Licensees Authorized To Manufacture or Initially Transfer Items Containing Radioactive Material for Sale or Distribution and Possess High-Risk Radioactive Material of Concern; Order Imposing Additional Security Measures (Effective Immediately)

I

The Licensees identified in Attachment 1 [1] to this Order hold licenses issued in accordance with the Atomic Energy Act of 1954, as amended, by the U.S. Nuclear Regulatory Commission (NRC or Commission) or an Agreement State authorizing them to manufacture or initially transfer items containing radioactive material for sale or distribution. Commission regulations at 10 CFR 20.1801 or equivalent Agreement State regulations require Licensees to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas. Commission regulations at 10 CFR 20.1802 or equivalent Agreement State regulations require Licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

II

On September 11, 2001, terrorists simultaneously attacked targets in New York, N.Y., and Washington, DC, utilizing large commercial aircraft as weapons. In response to the attacks and intelligence information subsequently obtained, the Commission issued a number of Safeguards and Threat Advisories to its Licensees in order to strengthen Licensees' capabilities and readiness to respond to a potential attack on a nuclear facility. The Commission has also communicated with other Federal, State and local government agencies and industry representatives to discuss and evaluate the current threat environment in order to assess the adequacy of security measures at licensed facilities. In addition, the Commission has been conducting a review of its safeguards and security programs and requirements.

As a result of its consideration of current safeguards and license requirements, as well as a review of information provided by the intelligence community, the Commission has determined that certain additional security measures are required to be implemented by Licensees as prudent measures to address the current threat environment. Therefore, the Commission is imposing the requirements set forth in Attachment 2 [2] on certain Manufacturing and Distribution Licensees identified in Attachment 1 of this Order who currently possess, or have near term plans to possess, high-risk radioactive material of concern. These requirements, which supplement existing regulatory requirements, will provide the Commission with reasonable assurance that the public health and safety and common defense and security continue to be adequately protected in the current threat environment. Attachment 3 of this Order contains the requirements for fingerprinting and criminal history record checks for individuals when a licensee's reviewing official is determining access to Safeguards Information or unescorted access to the radioactive materials. These requirements will remain in effect until the Commission determines otherwise.

The Commission concludes that the security measures must be embodied in an Order consistent with the established regulatory framework. Furthermore, the Commission has determined that some of the security measures contained in Attachment 2 of this Order contain Safeguards Information and will not be released to the public as per the NRC's ''Order Imposing Requirements for the Protection of Certain Safeguards Information'' (EA–08–161), regarding the protection of Safeguards Information. The Commission hereby provides notice that it intends to treat all violations of the requirements contained in Attachment 2 to the NRC's ''Order Imposing Requirements for the Protection of Certain Safeguards Information'' (EA–08–161), applicable to the handling and unauthorized disclosure of Safeguards Information as serious breaches of adequate protection of the public health and safety and the common defense and security of the United States. Access to Safeguards Information is limited to those persons who have established a need-to-know the information, are considered to be trustworthy and reliable, have been fingerprinted and undergone a Federal Bureau of Investigation (FBI) identification and criminal history records check in accordance with the NRC's ''Order Imposing Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information'' (EA–08–162). A need-to-know means a determination by a person having responsibility for protecting Safeguards Information that a proposed recipient's access to Safeguards Information is necessary in the performance of official, contractual, or licensee duties of employment. Individuals who have been fingerprinted and granted access to Safeguards Information by the reviewing official under the NRC's ''Order Imposing Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information'' (EA–08–162) do not need to be fingerprinted again for purposes of being considered for unescorted access.

This Order also requires that a reviewing official must consider the results of the Federal Bureau of Investigations criminal history records check in conjunction with other applicable requirements to determine whether an individual may be granted or allowed continued unescorted access. The reviewing official may be one that has previously been approved by NRC in accordance with the ''Order Imposing Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information'' (EA–08–162). Licensees may nominate additional reviewing officials for making unescorted access determinations in accordance with NRC Orders EA–08–162. The nominated reviewing officials must have access to Safeguards Information or require unescorted access to the radioactive material as part of their job duties.

To provide assurance that Licensees are implementing prudent measures to achieve a consistent level of protection to address the current threat environment, Manufacturing and Distribution Licensees identified in Attachment 1 to this Order shall implement the requirements identified in Attachments 2 and 3 to this Order. In addition, pursuant to 10 CFR 2.202, I

[1] Attachment 1 contains sensitive information and will not be released to the public.

[2] Attachment 2 contains some requirements that are SAFEGUARDS INFORMATION, and cannot be released to the public. The remainder of the requirements contained in Attachment 2 that are not SAFEGUARDS INFORMATION will be released to the public.

find that in light of the common defense and security matters identified above, which warrant the issuance of this Order, the public health, safety and interest require that this Order be effective immediately.

III

Accordingly, pursuant to Sections 81, 147, 149, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR § 2.202, 10 CFR Part 30, and 10 CFR Part 32, *it is hereby ordered, effective immediately, that all licensees identified in Attachment 1 to this order shall comply with the requirements of this order as follows:*

A. The Licensee shall, notwithstanding the provisions of any Commission or Agreement State regulation or license to the contrary, comply with the requirements described in Attachments 2 and 3 to this Order. The Licensee shall immediately start implementation of the requirements in Attachments 2 and 3 to the Order and shall complete implementation by February 10, 2009, or the first day that radionuclides of concern at or above threshold limits (i.e., high-risk radioactive material), also identified in Attachment 2, are possessed, whichever is later.

B.1. The Licensee shall, within twenty (20) days of the date of this Order, notify the Commission, (1) if it is unable to comply with any of the requirements described in Attachments 2 or 3, (2) if compliance with any of the requirements is unnecessary in its specific circumstances, or (3) if implementation of any of the requirements would cause the Licensee to be in violation of the provisions of any Commission or Agreement State regulation or its license. The notification shall provide the Licensee's justification for seeking relief from or variation of any specific requirement.

2. If the Licensee considers that implementation of any of the requirements described in Attachments 2 or 3 to this Order would adversely impact safe operation of the facility, the Licensee must notify the Commission, within twenty (20) days of this Order, of the adverse safety impact, the basis for its determination that the requirement has an adverse safety impact, and either a proposal for achieving the same objectives specified in Attachments 2 or 3 requirement in question, or a schedule for modifying the facility to address the adverse safety condition. If neither approach is appropriate, the Licensee must supplement its response to Condition B.1 of this Order to identify the condition as a requirement with which it cannot comply, with attendant justifications as required in Condition B.1.

C.1. In accordance with the NRC's ''Order Imposing Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information'' (EA–08–162) only the NRC-approved reviewing official shall review results from an FBI criminal history records check. The licensee may use a reviewing official previously approved by the NRC as its reviewing official for determining access to Safeguards Information or the licensee may nominate another individual specifically for making unescorted access to radioactive material determinations, using the process described in EA–08–162. The reviewing official must have access to Safeguards Information or require unescorted access to the radioactive material as part of their job duties. The reviewing official shall determine whether an individual may have, or continue to have, unescorted access to radioactive materials that equal or exceed the quantities in Attachment 2 to this Order. Fingerprinting and the FBI identification and criminal history records check are not required for individuals exempted from fingerprinting requirements under 10 CFR 73.61 [72 FR 4945 (February 2, 2007)]. In addition, individuals who have a favorably decided U.S. Government criminal history records check within the last five (5) years, or have an active federal security clearance (provided in each case that the appropriate documentation is made available to the Licensee's reviewing official), have satisfied the Atomic Energy Act of 1954, as amended, fingerprinting requirement and need not be fingerprinted again for purposes of being considered for unescorted access.

2. No person may have access to Safeguards Information or unescorted access to radioactive materials if the NRC has determined, in accordance with its administrative review process based on fingerprinting and an FBI identification and criminal history records check, either that the person may not have access to Safeguards Information or that the person may not have unescorted access to a utilization facility or radioactive material or other property subject to regulation by the NRC.

D. Fingerprints shall be submitted and reviewed in accordance with the procedures described in Attachment 3 to this Order. Individuals who have been fingerprinted and granted access to Safeguards Information by the reviewing official under Order EA–08–162, do not need to be fingerprinted again for purposes of being considered for unescorted access.

E. The Licensee may allow any individual who currently has unescorted access to radioactive materials, in accordance with this Order, to continue to have unescorted access without being fingerprinted, pending a decision by the reviewing official (based on fingerprinting, an FBI criminal history records check and a trustworthy and reliability determination) that the individual may continue to have unescorted access to radioactive materials that equal or exceed the quantities listed in Attachment 2. The licensee shall complete implementation of the requirements of Attachments 2 and 3 to this Order by February 10, 2009, or the first day that radionuclides of concern at or above threshold limits (i.e., high-risk radioactive material), also identified in Attachment 2, are possessed, whichever is later.

F.1. The Licensee shall, within twenty (20) days of the date of this Order, submit to the Commission a schedule for completion of each requirement described in Attachments 2 and 3.

2. The Licensee shall report to the Commission when they have achieved full compliance with the requirements described in Attachments 2 and 3.

G. Notwithstanding any provisions of the Commission's or an Agreement State's regulations to the contrary, all measures implemented or actions taken in response to this Order shall be maintained until the Commission determines otherwise.

Licensee responses to Conditions B.1, B.2, F.1, and F.2 above shall be submitted to the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. In addition, Licensee submittals that contain specific physical protection or security information considered to be Safeguards Information shall be put in a separate enclosure or attachment and, marked as ''SAFEGUARDS INFORMATION—MODIFIED HANDLING'' and mailed (no electronic transmittals i.e., no e-mail or FAX) to the NRC.

The Director, Office of Federal and State Materials and Environmental Management Programs, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

IV

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may,

submit an answer to this Order within twenty (20) days of the date of this Order. In addition, the Licensee and any other person adversely affected by this Order may request a hearing of this Order within twenty (20) days of the date of the Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made, in writing, to the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

The answer may consent to this Order. If the answer includes a request for a hearing, it shall, under oath or affirmation, specifically set forth the matters of fact and law on which the Licensee relies and the reasons as to why the Order should not have been issued. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d).

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007) and codified in pertinent part at 10 CFR Part 2, Subpart B. The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements associated with E-Filing, at least ten (10) days prior to the filing deadline the requestor must contact the Office of the Secretary by e-mail at *HEARINGDOCKET@NRC.GOV,* or by calling (301) 415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any NRC proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances when the requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html.* Information about applying for a digital ID certificate also is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.*

Once a requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for a hearing through EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the filer submits its document through EIE. To be timely, electronic filings must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request is filed so that they may obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397–4209 or locally, (301) 415–4737.

Participants who believe that they have good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville, Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, Participants are requested not to include copyrighted materials in their works.

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), the Licensee may, in addition to requesting a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section III above shall be final twenty (20) days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section III shall be final when the extension expires if a hearing request has not been received.

An answer or a request for hearing shall not stay the immediate effectiveness of this order.

Dated this 14th day of August 2008.

For The Nuclear Regulatory Commission.

Charles L. Miller,

Director, Office of Federal and State Materials and Environmental Management Programs.

Attachment 1: Service List of Materials Licensees—Redacted

Attachment 2: Additional Security Measures for Manufacturing and Distribution Materials Licensees (U)—(Revision 1)

These Additional Security Measures (ASMs) and new requirements are established to delineate licensee responsibility in response to the current threat environment. The following security measures apply to Radioactive Material Manufacturing and Distribution Licensees who, at any given time, possess greater than or equal to the quantities of concern of radioactive material defined in Table 1 (unless the licensee documents the basis for concluding that radioactive material possessed cannot be easily aggregated into quantities in excess of the limits defined in Table 1). As with the additional security measures previously provided to other licensees who possess risk significant radioactive sources, these increased security measures and requirements address licensees who are authorized to possess high-activity radioactive material which poses a high risk to human health if not managed safely and securely.

1. Establish a security zone (or zones). A security zone is an area, determined by the licensee, that provides for both isolation of radioactive material and access control.

a. Only use and store the radioactive material within the established security zone(s); and

b. The licensee shall demonstrate for each security zone, a means to deter, detect and delay any attempt of unauthorized access to licensed material. The security zone is not required to be the same as the restricted area or controlled area, as defined in 10 CFR Part 20 or equivalent agreement state regulations; and

c. Security zones can be permanent or temporary to meet transitory or intermittent business activities (such as during periods of maintenance, source delivery, source replacement, and temporary job sites). Different isolation/access control measures may be used for periods during which the security zone is occupied versus unoccupied.

2. Control access at all times to the security zone and limit admittance to those individuals who are approved and require access to perform their duties.

3. Implement a system to monitor, detect, assess and respond to unauthorized entries into or activities in the security zone.

a. [This paragraph contains SAFEGUARDS INFORMATION and will not be publicly disclosed]

b. Provide a positive measure to detect unauthorized removal of the radioactive material from the security zone; and

c. [This paragraph contains SAFEGUARDS INFORMATION and will not be publicly disclosed]

4. [This paragraph contains SAFEGUARDS INFORMATION and will not be publicly disclosed]

5. Licensees shall document the basis for concluding that there is reasonable assurance that individuals granted access to safeguards information or unescorted access to the security zone are trustworthy and reliable, and do not constitute an unreasonable risk for malevolent use of the regulated material. ''Access'' means that an individual could exercise some physical control over the material or device containing radioactive material.

a. The trustworthiness and reliability of individuals shall be determined based on a background investigation. The background investigation shall address at least the past 3 years and, as a minimum, include fingerprinting and a Federal Bureau of Investigation (FBI) criminal history check, verification of work or education references as appropriate to the length of employment, and confirmation of employment eligibility.

b. Fingerprints shall be submitted and reviewed in accordance with the procedures described in Attachment 3 to this Order.

c. A reviewing official that the licensee nominated and has been approved by the NRC, in accordance with NRC ''Order Imposing Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information,'' may continue to make trustworthiness and reliability determinations. The licensee may also nominate another individual specifically for making unescorted access determinations using the process identified in the NRC ''Order Imposing Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information.''

d. Individuals for whom the licensee has not made a determination of trustworthiness and reliability, based on the appropriate background investigation above, shall be escorted within the security zone to prevent unauthorized access or actions to the licensed radioactive material. The licensee shall also ensure these individuals are clearly identifiable as needing an escort while in the security zone.

6. Before transfer of radioactive materials that exceed the quantities in Table 1, Licensees shall:

a. [This paragraph contains SAFEGUARDS INFORMATION and will not be publicly disclosed]

b. [This paragraph contains SAFEGUARDS INFORMATION and will not be publicly disclosed]

c. Assure that the material is shipped to an address authorized in the license and that the address is valid,

d. Verify the address for deliveries to temporary job site, and

e. Document the verification or validation process.

7. For domestic highway and rail shipments of materials in quantities greater than or equal to the quantities in Table 1, per conveyance, the licensee shall:

a. Only use carriers who:

(1) Use established package tracking systems,

(2) Implement methods to assure trustworthiness of drivers,

(3) Maintain constant control and/or surveillance during transit, and

(4) Have the capability for immediate communication to summon appropriate response or assistance.

The licensee shall verify and document that the carrier employs the measures listed above.

b. Coordinate departure and arrival times with the recipient.

c. Immediately initiate an investigation with the carrier and intended recipient If the shipment does not arrive by close of business on the day of the previously coordinated arrival time. Not later than one hour after the time when, through the course of the investigation, it is determined the shipment has become lost or stolen, the licensee shall notify the appropriate local law enforcement agency, the NRC Operations Center at (301) 816–5100, and the appropriate Agreement State regulatory agency. If after 24 hours of initiating the investigation, the radioactive material cannot be located, it shall be presumed lost and the licensee shall immediately notify the NRC Operations Center and, for Agreement State licensees, the appropriate Agreement State regulatory agency.

d. In addition to a and b above, for highway and rail shipments of material in quantities greater than or equal to 100 times the quantities in Table 1, per conveyance, the licensee shall

implement the NRC Order for Additional Security Measures on the Transportation of Radioactive Material Quantities of Concern.

8. For imports and exports of material in quantities greater than the quantities in Table 1, per conveyance, the licensee shall follow the requirements in the Final Rule 10 CFR Part 110, July 1, 2005, (70 FR 37985 and 46066) Export and Import of Radioactive Materials: Security Policies.

9. The licensee shall protect pre-planning, coordinating, and reporting information required by ASM 7 related to shipments of radioactive material, and the radioisotopes identified in Table 1 as sensitive information (proprietary business financial or confidential). Licensees shall restrict access to this information to those licensee and contractor personnel with a need to know. Licensees shall require all parties receiving this information to protect it similarly. Information may be transmitted either in writing or electronically and shall be marked as ''Security-Related Information—Withhold Under 10 CFR 2.390.''

10. The licensee shall maintain all documentation required by these ASMs for a period of not less than three (3) years after the document is superseded or no longer effective.

TABLE 1—RADIONUCLIDES OF CONCERN

Radionuclide	Quantity of concern [1] (TBq)	Quantity of concern [2] (Ci)
Am–241	0.6	16
Am–241/BE	0.6	16
Cf–252	0.2	5.4
Cm–244	0.5	14
Co–60	0.3	8.1
Cs–137	1	27
Gd–153	10	270
Ir–192	0.8	22
Pm–147	400	11,000
Pu–238	0.6	16
Pu–239/Be	0.6	16
Ra–226 [3]	0.4	11
Se–75	2	54
Sr–90 (Y–90)	10	270
Tm–170	200	5,400
Yb–169	3	81
Combinations of radioactive materials listed above [4]	(5)	

[1] The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

[2] The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

[3] The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

[4] Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

[5] If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n, $A^{(i,n)}$, to the quantity of concern for radionuclide n, $Q^{(n)}$, listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc. * * * ≥ 1.

Guidance for Aggregation of Sources

NRC supports the use of the International Atomic Energy Association's (IAEA) source categorization methodology as defined in IAEA Safety Standards Series No. RS–G–1.9, ''Categorization of Radioactive Sources,'' (2005) (see *http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf*) and as endorsed by the agency's Code of Conduct for the Safety and Security of Radioactive Sources, January 2004 (see *http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf*). The Code defines a three-tiered source categorization scheme. Category 1 corresponds to the largest source strength (equal to or greater than 100 times the quantity of concern values listed in Table 1) and Category 3, the smallest (equal or exceeding one-tenth the quantity of concern values listed in Table 1). Additional security measures apply to sources that are equal to or greater than the quantity of concern values listed in Table 1, plus aggregations of smaller sources that are equal to or greater than the quantities in Table 1. Aggregation only applies to sources that are collocated.

Licensees who possess individual sources in total quantities that equal or exceed the Table 1 quantities are required to implement additional security measures. Where there are many small (less than the quantity of concern values) collocated sources whose total aggregate activity equals or exceeds the Table 1 values, licensees are to implement additional security measures.

Some source handling or storage activities may cover several buildings, or several locations within specific buildings. The question then becomes, ''When are sources considered collocated for purposes of aggregation?'' For purposes of the additional controls, sources are considered collocated if breaching a single barrier (e.g., a locked door at the entrance to a storage room) would allow access to the sources. Sources behind an outer barrier should be aggregated separately from those behind an inner barrier (e.g., a locked source safe inside the locked storage room). However, if both barriers are simultaneously open, then all sources within these two barriers are considered to be collocated. This logic should be continued for other barriers within or behind the inner barrier.

The following example illustrates the point: A lockable room has sources stored in it. Inside the lockable room, there are two shielded safes with additional sources in them. Inventories are as follows:

The room has the following sources outside the safes: Cf-252, 0.12 TBq (3.2 Ci); Co–60, 0.18 TBq (4.9 Ci), and Pu–

238, 0.3 TBq (8.1 Ci). Application of the unity rule yields: (0.12 ÷ 0.2) + (0.18 ÷ 0.3) + (0.3 ÷ 0.6) = 0.6 + 0.6 + 0.5 = 1.7. Therefore, the sources would require additional security measures.

Shielded safe #1 has a 1.9 TBq (51 Ci) Cs-137 source and a 0.8 TBq (22 Ci) Am-241 source. In this case, the sources would require additional security measures, regardless of location, because they each exceed the quantities in Table 1.

Shielded safe #2 has two Ir-192 sources, each having an activity of 0.3 TBq (8.1 Ci). In this case, the sources would not require additional security measures while locked in the safe. The combined activity does not exceed the threshold quantity 0.8 TBq (22 Ci).

Because certain barriers may cease to exist during source handling operations (e.g., a storage location may be unlocked during periods of active source usage), licensees should, to the extent practicable, consider two modes of source usage—''operations'' (active source usage) and ''shutdown'' (source storage mode). Whichever mode results in the greatest inventory (considering barrier status) would require additional security measures for each location.

Use the following method to determine which sources of radioactive material require implementation of the Additional Security Measures (ASMs):

- Include any single source equal to or greater than the quantity of concern in Table
- Include multiple collocated sources *of the same radionuclide* when the combined quantity equals or exceeds the quantity of concern
- For combinations of radionuclides, include multiple collocated sources of *different radionuclides* when the aggregate quantities satisfy the following unity rule: [(amount of radionuclide A) ÷ (quantity of concern of radionuclide A)] + [(amount of radionuclide B) ÷ (quantity of concern of radionuclide B)] + etc. * * * ≥ 1

Attachment 3: Requirements for Fingerprinting and Criminal History Checks of Individuals when Licensee's Reviewing Official is Determining Access to Safeguards Information or Unescorted Access to Radioactive Materials General Requirements

Licensees shall comply with the following requirements of this attachment.

1. Each Licensee subject to the provisions of this attachment shall fingerprint each individual who is seeking or permitted access to safeguards information (SGI) or unescorted access radioactive materials equal to or greater than the quantities listed in Attachment 2 to this Order. The Licensee shall review and use the information received from the Federal Bureau of Investigation (FBI) and ensure that the provisions contained in this Order and this attachment are satisfied.

2. The Licensee shall notify each affected individual that the fingerprints will be used to secure a review of his/her criminal history record and inform the individual of the procedures for revising the record or including an explanation in the record, as specified in the ''Right to Correct and Complete Information'' section of this attachment.

3. Fingerprints for access to SGI or unescorted access need not be taken if an employed individual (*e.g.*, a Licensee employee, contractor, manufacturer, or supplier) is relieved from the fingerprinting requirement by 10 CFR 73.59 for access to SGI or 10 CFR 73.61 for unescorted access, has a favorably-decided U.S. Government criminal history check (*e.g.* National Agency Check, Transportation Worker Identification Credentials in accordance with 49 CFR Part 1572, Bureau of Alcohol Tobacco Firearms and Explosives background checks and clearances in accordance with 27 CFR Part 555, Health and Human Services security risk assessments for possession and use of select agents and toxins in accordance with 27 CFR Part 555, Hazardous Material security threat assessments for hazardous material endorsement to commercial drivers license in accordance with 49 CFR Part 1572, Customs and Border Patrol's Free and Secure Trace Program [1]) within the last five (5) years, or has an active federal security clearance. Written confirmation from the Agency/employer which granted the federal security clearance or reviewed the criminal history check must be provided for either of the latter two cases. The Licensee must retain this documentation for a period of three (3) years from the date the individual no longer requires access to SGI or unescorted access to radioactive materials associated with the Licensee's activities.

4. All fingerprints obtained by the Licensee pursuant to this Order must be submitted to the Commission for transmission to the FBI.

5. The Licensee shall review the information received from the FBI and consider it, in conjunction with the trustworthy and reliability requirements of this Order, in making a determination whether to grant, or continue to allow, access to SGI or unescorted access to radioactive materials.

6. The Licensee shall use any information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for access to SGI or unescorted access to radioactive materials equal to or greater than the quantities used in Attachment 2 to this Order.

7. The Licensee shall document the basis for its determination whether to grant, or continue to allow, access to SGI or unescorted access to radioactive materials equal to or greater than the quantities used in Attachment 2 to this Order.

Prohibitions

A Licensee shall not base a final determination to deny an individual access to radioactive materials solely on the basis of information received from the FBI involving: an arrest more than one (1) year old for which there is no information of the disposition of the case, or an arrest that resulted in dismissal of the charge or an acquittal.

A Licensee shall not use information received from a criminal history check obtained pursuant to this Order in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall the Licensee use the information in any way which would discriminate among individuals on the basis of race, religion, national origin, sex, or age.

Procedures for Processing Fingerprint Checks

For the purpose of complying with this Order, Licensees shall, using an appropriate method listed in 10 CFR 73.4, submit to the NRC's Division of Facilities and Security, Mail Stop T–6E46, one completed, legible standard fingerprint card (Form FD–258, ORIMDNRCOOOZ) or, where practicable, other fingerprint records for each individual seeking access to SGI or unescorted access to radioactive materials equal to or greater than the quantities used in Attachment 2 to this Order, to the Director of the Division of Facilities and Security, marked for the attention of the Division's Criminal History Check Section. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission,

[1] The FAST program is a cooperative effort between the Bureau of Customs and Border Patrol and the governments of Canada and Mexico to coordinate processes for the clearance of commercial shipments at the U.S.-Canada and U.S.-Mexico borders. Participants in the FAST program, which requires successful completion of a background records check, may receive expedited entrance privileges at the northern and southern borders.

Washington, DC 20555–0001, by calling (301) 415–7232, or by e-mail to *forms.resource@nrc.gov.* Practicable alternative formats are set forth in 10 CFR 73.4. The Licensee shall establish procedures to ensure that the quality of the fingerprints taken results in minimizing the rejection rate of fingerprint cards due to illegible or incomplete cards.

The NRC will review submitted fingerprint cards for completeness. Any Form FD–258 fingerprint record containing omissions or evident errors will be returned to the Licensee for corrections. The fee for processing fingerprint checks includes one resubmission if the initial submission is returned by the FBI because the fingerprint impressions cannot be classified. The one free re-submission must have the FBI Transaction Control Number reflected on the re-submission. If additional submissions are necessary, they will be treated as initial submittals and will require a second payment of the processing fee.

Fees for processing fingerprint checks are due upon application (Note: other fees may apply to obtain fingerprints from your local law enforcement agency). Licensees should submit payments electronically via *http://www.pay.gov.* Payments through Pay.gov can be made directly from the Licensee's credit/debit card. Licensees will need to establish a password and user ID before they can access Pay.gov. To establish an account, Licensee requests must be sent to *paygo@nrc.gov.* The request must include the Licensee's name, address, point of contact, e-mail address, and phone number. The NRC will forward each request to Pay.gov and someone from Pay.gov will contact the Licensee with all of the necessary account information. Licensees shall make payments for processing before submitting applications to the NRC. Combined payment for multiple applications is acceptable. Licensees shall include the Pay.gov payment receipt(s) along with the application(s). For additional guidance on making electronic payments, contact the Facilities Security Branch, Division of Facilities and Security, at (301) 415–7404.

Alternatively, licensees may also submit payment with the application for processing fingerprints by fingerprints by corporate check, certified check, cashier's check, or money order, made payable to ''U.S. NRC.'' Combined payment for multiple applications is acceptable.

The application fee (currently $36) is the sum of the user fee charged by the FBI for each fingerprint card or other fingerprint record submitted by the NRC on behalf of a Licensee, and an NRC processing fee, which covers administrative costs associated with NRC handling of Licensee fingerprint submissions. The Commission will directly notify Licensees subject to this regulation of any fee changes.

The Commission will forward to the submitting Licensee all data received from the FBI as a result of the Licensee's application(s) for criminal history checks, including the FBI fingerprint record.

Right To Correct and Complete Information

Prior to any final adverse determination, the Licensee shall make available to the individual the contents of any criminal records obtained from the FBI for the purpose of assuring correct and complete information. Written confirmation by the individual of receipt of this notification must be maintained by the Licensee for a period of one (1) year from the date of the notification. If, after reviewing the record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, or update the alleged deficiency, or to explain any matter in the record, the individual may initiate challenge procedures. These procedures include either direct application by the individual challenging the record to the agency (*i.e.*, law enforcement agency) that contributed the questioned information, or direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Assistant Director, Federal Bureau of Investigation Identification Division, Washington, DC 20537–9700 (as set forth in 28 CFR Part 16.30 through 16.34). In the latter case, the FBI forwards the challenge to the agency that submitted the data and requests that agency to verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. The Licensee must provide at least ten (10) days for an individual to initiate an action challenging the results of an FBI criminal history records check after the record is made available for his/her review. The Licensee may make a final determination on access to SGI or unescorted access to radioactive materials equal to or greater than the quantities used in Attachment 2 to this Order based upon the criminal history record only upon receipt of the FBI's ultimate confirmation or correction of the record. Upon a final adverse determination on access to SGI or unescorted access to radioactive materials equal to or greater than the quantities used in Attachment 2 to this Order, the Licensee shall provide the individual its documented basis for denial. Access to SGI or unescorted access to radioactive materials equal to or greater than the quantities used in Attachment 2 to this Order shall not be granted to an individual during the review process.

Protection of Information

1. Each Licensee who obtains a criminal history record on an individual pursuant to this Order shall establish and maintain a system of files and procedures for protecting the record and the personal information from unauthorized disclosure.

2. The Licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his/her representative, or to those who have a need to access the information in performing assigned duties in the process of determining access to SGI or unescorted access to radioactive materials equal to or greater than the quantities used in Attachment 2 to this Order. No individual authorized to have access to the information may re-disseminate the information to any other individual who does not have a need-to-know.

3. The personal information obtained on an individual from a criminal history record check may be transferred to another Licensee if the Licensee holding the criminal history record receives the individual's written request to re-disseminate the information contained in his/her file, and the gaining Licensee verifies information such as the individual's name, date of birth, social security number, sex, and other applicable physical characteristics for identification purposes.

4. The Licensee shall make criminal history records, obtained under this section, available for examination by an authorized representative of the NRC to determine compliance with the regulations and laws.

5. The Licensee shall retain all fingerprint and criminal history records received from the FBI, or a copy if the individual's file has been transferred, for three (3) years after termination of employment or denial to access SGI or unescorted access to radioactive materials equal to or greater than the quantities used in Attachment 2 to this Order. After the required three (3) year period, these documents shall be destroyed by a method that will prevent

reconstruction of the information in whole or in part.

[FR Doc. E8–19545 Filed 8–21–08; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Availability of Regulatory Issue Summary 2008–18; Information on Requests for Extending Use of Expiring Transportation Packages

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The NRC staff has issued Regulatory Issue Summary (RIS) 2008–18, Information on Requests for Extending Use of Expiring Transportation Packages. The RIS is intended to provide information to licensees and certificate holders who may request NRC consideration on a case-by-case basis for limited domestic use of transportation packages beyond the October 1, 2008, expiration date. The RIS does not impose any additional regulatory requirements on NRC licensees.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy Osgood, Project Manager, Licensing Branch, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492–3326; fax number: (301) 492–3348; e-mail: *nancy.osgood@nrc.gov.*

SUPPLEMENTARY INFORMATION: The attachment to this **Federal Register** notice contains RIS 2008–18, Information on Requests for Extending Use of Expiring Transportation Packages. RIS 2008–18 is also available electronically in the NRC's Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. RIS 2008–18 can be found in ADAMS at accession number ML081920729. If you do not have access to ADAMS, or if there are problems accessing documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference Staff at 1–800–397–4209, 301–415–4737, or e-mail *pdr.resource@nrc.gov.* This document may also be viewed electronically on the public computers located at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland, this 14th day of August 2008.

For the Nuclear Regulatory Commission.

Eric Benner,

Chief, Licensing Branch, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards.

Attachment

Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC 20555–0001. August 14, 2008.

NRC Regulatory Issue Summary 2008–18; Information on Requests for Extending Use of Expiring Transportation Packages

Addressees

Users of, or certificate holders for, transportation packages that expire on October 1, 2008, specifically:

(a) Type B packages, that the U.S. Nuclear Regulatory Commission (NRC) has previously approved, but not designated as B(U), B(M), B(U)F, or B(M)F in the identification number of the NRC Certificate of Compliance, or Type AF transportation packages, that NRC approved before September 6, 1983; or

(b) Existing Type B packagings, constructed to U.S. Department of Transportation (DOT) Specification 6M, 20WC, or 21WC, conforming in all aspects to the requirements of 49 CFR Subchapter C, in effect on October 1, 2003, or existing fissile material packagings constructed to DOT Specification 6L, 6M, or 1A2, conforming in all aspects to the requirements of 49 CFR Subchapter C, in effect on October 1, 2003.

Intent

Sections 71.19(a) and 71.20 of 10 Code of Federal Regulations (CFR) part 71 expire on October 1, 2008. Section 71.19(a) authorizes the use of Type B transportation packages, previously approved by NRC, but not designated as B(U), B(M), B(U)F, or B(M)F in the identification number on the NRC Certificate of Compliance or Type AF transportation packages approved by NRC, before September 6, 1983. Section 71.20 authorizes use of DOT specification containers for fissile material or for a Type B quantity of radioactive material, as specified in DOT regulations at 49 CFR parts 173 and 178. NRC is issuing this regulatory issue summary (RIS) to inform addressees regarding information that will be considered in requests for extending use of these packages beyond October 1, 2008.

Background Information

On January 26, 2004, NRC published a final rule in the **Federal Register** (69 FR 3698), amending its transportation regulations in Part 71, to be compatible with the latest version of the International Atomic Energy Agency (IAEA) ''Regulations for the Safe Transport of Radioactive Material'' (IAEA Safety Standards Series No. TS–R–1). NRC coordinated this rulemaking with DOT, since NRC and DOT jointly regulate the safety of radioactive material in transport. In this rulemaking, NRC and DOT implemented a planned phaseout of the Type B and fissile material transportation packages described above. The phaseout is to be completed by October 1, 2008 (when the regulations authorizing use of these packages expire). Certain licensees have indicated that they may need to make shipments in these packages after the October 1, 2008, expiration date.

Summary of Issue

NRC regulations for packaging and transportation of radioactive materials are contained in part 71. These regulations are amended from time to time, to harmonize them with periodic revisions to IAEA regulations, which are used internationally. Grandfathering provisions, such as 10 CFR 71.19(a) and 71.20, have historically been included both in NRC and IAEA regulations. The grandfathering provisions allow continued use, with some conditions, of transportation packages approved to previous editions of the regulations. The purpose of the grandfathering provisions is to minimize cost and impact on implementing the changes to the regulations.

In the January 2004 rulemaking, NRC adopted revised regulations in part 71, to harmonize with the 1996 edition of the IAEA regulations (TS–R–1), which no longer authorized the use of the Type B and fissile material transportation packages described above. Among other changes, the 10 CFR 71.19(a) and 10 CFR 71.20 grandfathering provisions were adopted to allow continued use of these Type B and fissile material transportation packages until October 1, 2008.

Certain licensees and certificate holders have indicated that there may be instances where limited use of these packages may be needed beyond the October 1, 2008, expiration date. This RIS is intended to provide information to licensees and certificate holders in requesting authorization for such limited use.

NRC Review of Requests

Requests for limited use of these packages after the October 1, 2008, expiration date must address all five elements listed below. NRC will consider these requests on a case-by-case basis. Applicants should note that these requests will not be considered a form of certificate renewal, either under 10 CFR 71.38 or any other NRC regulation.

Licensees or certificate holders who have identified the need to use these packages should provide the following information to NRC and DOT before the October 1, 2008, expiration date:

(1) *Package Information.* NRC Certificate of Compliance Number or DOT Specification Number.

(2) *Identification of Shipments.* (a) Number of shipments; (b) number of packages per shipment; (c) packaging serial numbers; (d) package contents; (e) end use of the radioactive material; (f) shipment origin and destination; (g) mode; (h) general timeframe (e.g., first quarter 2009); and (i) date last shipment will be completed.

(3) *Reasons for Requesting Extended Use.* Justification for extending the use of expiring packages must describe why acquiring replacement packages is not practical and

why shipments cannot be made before the October 1, 2008, expiration date. The justification must demonstrate that: (a) There are no alternative domestically approved packages available; (b) the contents cannot be reconfigured such that transport can be conducted in accordance with the regulations; and (c) the transport schedule cannot be adjusted so as to be conducted in accordance with the regulations. The justification must also describe any good-faith efforts to acquire replacement packages that meet the current package performance requirements, including a detailed description of past activities and the current status of acquiring replacement packages. In addition, any adverse impacts that will result if the shipment is not conducted should be fully described.

(4) *Safety Justification for Continued Use and Proposed Compensatory Measures.* Since the expiring package designs may lack safety enhancements included in newer designs, the request must include a safety justification for continued use and a description of compensatory measures that will be used to provide an equivalent level of safety. Examples of compensatory measures that may be considered are: (a) Special package inspections, tests, or determinations that ensure that the packaging is in unimpaired physical condition; (b) transport by exclusive use; (c) transport during time of low road usage; and (d) accompaniment of shipment by escort equipped to effect a recovery in an emergency situation or in case of a transportation accident.

(5) *A Plan and Schedule to Acquire Replacement Packages or Complete Necessary Shipments.* Details about the planned acquisition of replacement packages must be provided, along with key milestones, and proposed implementation dates, unless the licensee can show why acquiring a replacement package is not practical and why shipments cannot be made before the October 1, 2008, expiration date.

Filing Requests for Extension

Requests to extend use of these packages should be sent to NRC, with a copy sent separately to DOT (applications to DOT should be in accordance with 49 CFR 107.105). The requests should be addressed as follows:

ATTN: Document Control Desk, Director, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–001;

ATTN: Special Permits, PHH–31, Associate Administrator for Hazardous Material Safety, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Ave., SE., Washington, DC 20590.

Backfit Discussion

This RIS outlines information that licensees should consider for incorporation in voluntary submittals for extending the use of the subject transportation packages. The identified information will assist the NRC in the regulatory process and aids licensees in developing thorough submittals. Any requests to extend the use of the subject transportation packages are proposed by licensees and are therefore not backfits. Further, this RIS requires no action or written response and therefore is not a backfit. Consequently, the staff did not perform a backfit analysis.

Federal Register Notification

A notice of opportunity for public comment on this RIS was not published in the **Federal Register** because it is informational and pertains to a staff position that does not represent a departure from current regulatory status and practice. This RIS is being published in the **Federal Register** for information.

Congressional Review Act

This RIS is not a rule, as designated by the Congressional Review Act (5 U.S.C. 801–808) and, therefore, is not subject to the Act.

Paperwork Reduction Act Statement

This Regulatory Issue Summary contains information collections that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). These information collections were approved by the Office of Management and Budget, approval number 3150–0008.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, a request for information collection.

Contact

Please direct any questions about this matter to the technical contact listed below.

E. William Brach, Director,
Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards.

Technical Contact: Nancy L. Osgood, NMSS/SFST, (301) 492–3326, e-mail: *Nancy.Osgood@nrc.gov.*

[FR Doc. E8–19553 Filed 8–21–08; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Proposed New Information Collection Requests Under OMB Review

AGENCY: Peace Corps.

ACTION: Notice of public use form review request to the Office of Management and Budget (OMB).

SUMMARY: The Peace Corps Office of Communications invites comments on the information collection request as required pursuant to the Paperwork Reduction Act of 1981 (44 U.S.C. Chapter 35). This notice announces that the Peace Corps Office of Communications has submitted to the Office of Management and Budget a request to approve the use of: PC–836, Peace Corps 50th Anniversary Archive Submission Form (On-line Version) (06/2008); PC–837, 50th Anniversary Archive Project Material Submission Authorization and Agreement (Print Version) (06/2008); PC–839, 50th Anniversary Archive Submission Guidelines (06/2008); and PC–841, 50th Anniversary Archive (Print Version) (06/2008). The purpose of this notice is to allow for comments on whether the proposed collection of information is necessary for proper performance of the functions of the Peace Corps' Office of Communications; including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; ways to enhance the quality, utility, and clarify of the information to be collected; and ways to minimize the burden of the collection of information to on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of technology. The initial **Federal Register** notice was published on July 2, 2008, Volume 73, No. 128, pgs. 37997–37998 for 60 days. Also available at GPO Access: *wais.access.gpo.gov.* No comments, inquiries or responses to the notice were received. Comments may be directed to: Stacia Clifton, 50th Anniversary Archive Project Manager, Peace Corps, Office of Communications, 1111 20th Street, NW., Washington, DC 20256. Ms. Clifton can also be contacted by telephone at 202–692–2234 or by e-mail at *archive@peacecorps.gov.* Comments should be received on or before September 22, 2008.

Information Collection Abstract

Title: 50th Anniversary Archive Submission Form.

Need for and Use of This Information: The Peace Corps is collecting contact information, stories, photos and historical documents related to their Peace Corps service from Returned Peace Corps Volunteers. Submissions will be received electronically through an online submission form. The information will be used in informational and promotional articles, exhibits and events celebrating the history of the Peace Corps.

Respondents: Returned Peace Corps Volunteers.

Respondents' Obligation to Reply: Voluntary.

Burden on the Public:

a. *Annual reporting burden:* 250 hours.

b. *Annual record keeping burden:* 50 hours.

c. *Estimated average burden per response:* 15 minutes.

d. *Frequency of response:* One-time.

e. *Estimated number of respondents:* 3000.

f. *Estimated cost to respondents:* $0.00/$0.00.

Dated: August 15, 2008.

Wilbert Bryant,

Associate Director for Management.

[FR Doc. E8–19511 Filed 8–21–08; 8:45 am]

BILLING CODE 6051–01–P

POSTAL REGULATORY COMMISSION

[Docket No. MC2008–7, CP2008–16, CP2008–17; Order No. 98]

Administrative Practice and Procedure; Postal Service

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission has established formal dockets to consider a formal request to add a new product to the competitive product list for prices not of general applicability and incorporates a notice of execution of two related contracts. The Commission's action will provide for public input and for a review to determine consistency with applicable statutory requirements.

DATES: Comments are due August 27, 2008.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202–789–6820 or *stephen.sharfman@prc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

On August 8, 2008, the Postal Service filed a formal request (with attachments) to add a new product to the competitive product list for prices not of general applicability.[1] The Request incorporates notice of (1) issuance of the Governors' Decision authorizing the new product; (2) the execution of two related contracts; and (3) submission of supporting material under seal.[2]

Request. The Request was filed pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.* Substantively, it seeks the addition of a shell classification in the competitive product list for a product referred to as Global Plus 2 Negotiated Service Agreements. Prices for this product, by the terms of the Governors' Decision, are established by setting price floor and price ceiling formulas in the contracts.

The Request also addresses the Postal Service's interest in confidentiality; presents proposed Mail Classification Schedule (MCS) language; cites the Cebello Statement with respect to satisfaction of pertinent Commission rules; and discusses reasons why the Global Plus 2 contracts should be deemed functionally equivalent. Request at 2–7. It affirmatively notes that the contracts include retroactivity provisions.[3] *Id.* at 7–9.

Related contracts. The Postal Service contemporaneously filed contracts related to the proposed new product listing pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. It maintains that both contracts, by virtue of their terms, fit within the proposed MCS language. It asks that the contracts be added as one product to the competitive product list for prices not of general applicability. *Id.* at 1. It further notes that both contracts are set to expire July 1, 2009. *Id.* at 2.

II. Notice of Filings

The Commission establishes Docket Nos. MC2008–7, CP2008–16 and CP2008–17 for consideration of the Request pertaining to Global Plus 2 and the two related contracts. In keeping with recent practice, these dockets are addressed on a consolidated basis for purposes of this Order; however, future filings should be made in the specific docket in which issues being addressed pertain. Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642. Comments are due no later than August 27, 2008. The public portions of these filings can be accessed via the Commission's Web site (*www.prc.gov*).

The Commission appoints Paul L. Harrington to serve as Public Representative in the captioned filings.

It is Ordered:

1. The Commission establishes Docket Nos. MC2008–7, CP2008–16 and CP2008–17 for consideration of the matters raised in each docket.

2. The Commission, pursuant to 39 U.S.C. 505, appoints Paul L. Harrington to serve as officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons on issues in these proceedings are due no later than August 27, 2008.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Issued August 13, 2008.

Judith M. Grady,

Acting Secretary.

[FR Doc. E8–19439 Filed 8–21–08; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2008–6, CP2008–14, CP2008–15; Order No. 97]

Administrative Practice and Procedure; Postal Service

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission has established formal dockets to consider three related Postal Service filings. The filings concern prices and classification changes for competitive products not of general applicability involving foreign postal administrations. The Commission's action will provide for public input and for a review to determine consistency with applicable statutory requirements.

DATES: Comments are due August 26, 2008.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202–789–6820 or *stephen.sharfman@prc.gov.*

SUPPLEMENTARY INFORMATION: On August 5, 2008, the Postal Service filed three requests incorporating notices, pursuant to 39 U.S.C. 3642, 39 CFR 3030 *et seq.*,

[1] *See* Request of the United States Postal Service to Add Global Plus 2 Negotiated Service Agreements to the Competitive Product List, and Notice of Filing (Under Seal) the Enabling Governors' Decision and Two Functionally Equivalent Agreements, August 8, 2008 (Request). Attachment 1 to the Request consists of Decision of the Governors of the United States Postal Service on the Establishment of Prices and Classifications for Global Direct, Global Bulk Economy, and Global Plus Contracts (Governors' Decision No. 08–10), July 16, 2008 (Governors' Decision). The Governors' Decision includes its own set of attachments presenting proposed classification language, pricing formulas and analyses, and the certification required under Commission rules. In the Request as filed, portions of the Governors' Decision and some of the attachments are redacted. Attachment 2 to the Request is the Statement of Supporting Justification provided by Frank Cebello, Executive Director of Global Business Management for the Postal Service (Cebello Statement) in the capacity of sponsor of the instant Request.

[2] This material includes an unredacted version of the enabling Governors' Decision, the record of proceedings, and other documents addressing compliance with 39 CFR 3015.5.

[3] The Postal Service states that the retroactivity provisions were intended to sustain customer relationships and avoid an interruption in service given uncertainty about the timing of review of the new Global Plus 2 contracts; however, it further notes that based on the Commission's decision and guidance in Order No. 85 (which was issued after the Global Plus 2 contracts were executed), it no longer intends to present future contracts to the Commission with retroactivity provisions. Instead, it will avail itself of the procedure for expedited consideration of requests for temporary relief when warranted. Request at 9.

which have been assigned to Docket Nos. MC2008–6, CP2008–14 and CP2008–15, announcing prices and classification changes for competitive products not of general applicability.[1] The request in Docket No. MC2008–6 informs the Commission that ''the Governors have established prices and classifications not of general applicability for Inbound Direct Entry Contracts with Foreign Postal Administrations,'' and attaches a redacted copy of the Governors' Decision.[2] *See* Request, Attachment 1. The Postal Service also attached a revision of the draft Mail Classification Schedule (MCS) (section 2612) concerning Inbound Direct Entry Contracts to the Notice.[3] *See* Request, Attachment 1, Attachment A.

In support of these dockets, the Postal Service filed a Statement of Supporting Justification of Pranab Shah. *See* Request, Attachment 2. The Postal Service has also filed materials under seal, including the unredacted Governors' Decision in Docket No. MC2008–6. The Postal Service claims that ''[p]rices and other contract terms relating to the foreign posts' processes and procedures are highly confidential in the business world * * * [and that its] ability * * * to negotiate individual contracts would be severely compromised if prices * * * [for] these types of agreements were publicly disclosed.'' Request at 2–3.

Docket Nos. CP2008–14 and CP2008–15 announce specific Inbound Direct Entry Contracts that the Postal Service has entered into with the individual Foreign Postal Administrations, namely China Post Group and Hong Kong Post, respectively.[4] *Id.* In support of these dockets, the Postal Service has also filed materials, including the contracts and supporting certifications, under seal.[5]

The Postal Service's filings in these dockets are related. Docket No. MC2008–6 establishes, in essence, a shell classification, while Docket Nos. CP2008–14 and CP2008–15 are specific agreements negotiated pursuant to the conditions of the shell classification. Given this interrelationship, the Commission reviews these proceedings together in this Order.[6]

In Order No. 43, the Commission issued regulations establishing a modern system of rate regulation, including a list of competitive products. Docket No. RM2007–1, Order Establishing Ratemaking Regulations for Market Dominant and Competitive Products, October 29, 2007, paras. 3061 and 4013. Among other things, the Commission determined that each negotiated service agreement would initially be classified as a separate product. The Commission also acknowledged, however, the possibility of grouping substantially equivalent agreements as a single product if they exhibit similar cost and market characteristics. *Id.,* paras. 2177 and 3001. In its filings, the Postal Service contends that these two agreements are premised on similar cost and market characteristics and provides arguments to support this claim. Request at 5–6. Thus, the Postal Service requests that the Commission classify the two agreements filed in Docket Nos. CP2008–14 and CP2008–15 as part of the same product.

Interested persons may express views and offer comments on whether the planned changes are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642. Comments are due no later than August 26, 2008.

Pursuant to 39 U.S.C. 505, Paul L. Harrington is designated to serve as officer of the Commission (Public Representative) to represent the interests of the general public in the above-captioned dockets.

It is Ordered:

1. Docket Nos. MC2008–6, CP2008–14, and CP2008–15 are established to consider the Postal Service Request and related contracts referred to in the body of this Order.

2. Comments by interested persons on issues in these proceedings are due no later than August 26, 2008.

3. The Commission designates Paul L. Harrington as Public Representative to represent the interests of the general public in these proceedings.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.
Issued August 13, 2008.

Judith M. Grady,

Acting Secretary.

[FR Doc. E8–19446 Filed 8–21–08; 8:45 am]

BILLING CODE 7710–FW–P

[1] Case captions for cases such as those involving negotiated agreements for competitive products should be standardized. The first line in the caption should list ''Competitive Product Prices''. The second line should list the product and the docket of the case that created that product. The third line should list the contracting party or ''Negotiated Service Agreement'' if the contracting party is confidential information.

[2] Request of United States Postal Service to Add Inbound Direct Entry Contracts With Foreign Postal Administrations to the Competitive Product List, and Notice of Filing (Under Seal) The Enabling Governors' Decision and Two Functionally Equivalent Contracts with Foreign Posts, August 5, 2008 (Request).

[3] The draft MCS remains under review. The Commission anticipates providing interested persons an opportunity to comment on the draft MCS in the near future.

[4] The Commission characterizes the Governors' Decision and associated materials filed in Docket No. MC2008–6 as material that supports the specific negotiated service agreements filed in Docket Nos. CP2008–14 and CP2008–15.

[5] *See* PRC Order No. 95, August 11, 2008, at 2 regarding the filing of certifications under seal.

[6] While this Order treats these proceedings together due to their interrelated nature, future filings should be made in the docket related to the issues being addressed.

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of: Birman Managed Care, Inc. (n/k/a Alcar Chemical Group, Inc.), Cluster Technology Corp., Consolidated Growers and Processors, Inc., Global Network, Inc., Micro-Integration Corp., Monsoon International Manufacturing & Distribution, Inc., Montt International Corp., Pony Express U. S. A., Inc., SUMmedia.com, Inc., and Sunflower USA, Ltd.; Order of Suspension of Trading

August 20, 2008

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Birman Managed Care, Inc. (n/k/a Alcar Chemical Group, Inc.) because it has not filed any periodic reports since the period ended March 31, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Cluster Technology Corp. because it has not filed any periodic reports since March 8, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Consolidated Growers and Processors, Inc. because it has not filed any periodic reports since January 5, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Global Network, Inc. because it has not filed any periodic reports since the period ended September 30, 2003.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Micro-Integration Corp. because it has not filed any periodic reports since December 31, 1999.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Monsoon International Manufacturing & Distribution, Inc. because it has not filed any periodic reports since the period ended January 21, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Montt International Corp. because it has not filed any periodic reports since February 14, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Pony Express U. S. A., Inc. because it has not filed any periodic reports since the period ended September 30, 2004.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of SUMmedia.com, Inc. because it has not filed any periodic reports since the period ended September 30, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Sunflower USA, Ltd. because it has not filed any periodic reports since the period ended February 29, 2000.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on August 20, 2008, through 11:59 p.m. EDT on September 3, 2008.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E8–19634 Filed 8–20–08; 4:15 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58378; File No. SR–Amex–2008–67]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Modifying the Definition of ''Independent Director'' in the Amex Company Guide

August 18, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, as amended (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 15, 2008, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section 803 of the Amex Company Guide (the ''Company Guide'') to modify the definition of ''independent director.'' The text of the proposed rule change is available on the Amex's Web site at *http://www.amex.com*, the Office of the Secretary, the Amex and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Amex has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 803(A)(2)(b) of the Company Guide generally precludes a director of a listed issuer from being considered ''independent'' if the director (or an immediate family member of a director) received more than $100,000 in compensation from the issuer or any parent or subsidiary of the issuer within any twelve-month period in the three years preceding the determination of the director's independence status. The Exchange proposes to raise this amount to $120,000 to conform its independence standard in this respect with a NASDAQ Stock Market LLC (''Nasdaq'') rule change just approved by the Commission and a similar proposal submitted and pending before the Commission by the New York Stock Exchange LLC (''NYSE'').[3]

In addition, the proposed change will harmonize the Exchange's independence standards with the existing $120,000 disclosure threshold applicable to related party transactions set by the Commission in Regulation S–K, Item 404.[4] Use of this consistent standard will enhance the Exchange's ability to assess compliance with the independent director requirements because listed issuers are uniformly required under Item 404 of Regulation S–K to disclose compensation to directors in excess of $120,000, but are not necessarily required to disclose compensation between $100,000 and $120,000. Further, the Exchange believes that by making its ''bright line'' standard with respect to the maximum amount of compensation a director (or an immediate family member of a director) can receive from the issuer (or any parent or subsidiary) consistent with the equivalent standard of Nasdaq and proposed by NYSE, it will provide a uniform standard for issuers to understand and apply. However, the Exchange notes that even if a director passes the ''bright line'' standard as proposed to be amended, an issuer's board of directors must still make an affirmative determination that such director has no relationship with the issuer that would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director.[5]

[1] 15 U.S.C. 78s(b)(l).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 58335 (August 8, 2008) (SR–NASDAQ–2008–053) (approving similar modifications to NASDAQ Rule 4200(a)(15)(B) and IM–4200) (Release No. 34–58335); and 58367 (August 15, 2008) (proposing similar modifications to Section 303A.02 of the NYSE Listed Company Manual).

[4] *See* 17 CFR 229.404 and 17 CFR 228.404; *see also* Securities Exchange Act Release No. 54302A (August 29, 2006), 71 FR 53158 (September 8, 2006).

[5] *See* Section 803(A)(2) of the Company Guide.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the proposal will align the Exchange's independent director standards with those of Nasdaq and NYSE, as well as with the Commission's disclosure requirements, thereby providing a uniform standard for issuers to understand and apply.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange did not receive any written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Amex has designated the proposed rule change as one that: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days from the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. In addition, as required under Rule 19b–4(f)(6)(iii),[8] the Amex provided the Commission with written notice of its intention to file the proposed rule change, along with a brief description of the text of the proposed rule change, at least five business days prior to filing the proposal, or such shorter time as designated by the Commission.[9] Therefore, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11]

The Amex has further requested the Commission to waive the 30-day operative delay. The Commission hereby grants Amex's request.[12] Waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the Amex proposal is consistent with a proposal by Nasdaq that recently was approved by the Commission.[13] The Commission notes that no comments were received on the Nasdaq proposal. Therefore, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest and designates the proposed rule change as operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Amex–2008–67 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2008–67. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Amex–2008–67 and should be submitted on or before September 12, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–19551 Filed 8–21–08; 8:45 am]

BILLING CODE 8010–01–P

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 17 CFR 240.19b–4(f)(6)(iii).

[9] The Exchange has requested that the Commission waive the 5-day pre-filing notice requirement under Rule 19b–4(f)(6)(iii) given that the instant rule filing was originally made pursuant to Section 19(b)(2) of the Act on August 13, 2008, and Commission staff requested on August 14, 2008 that the filing be re-submitted pursuant to Section 19(b)(3)(A). The Commission grants such waiver.

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] For purposes of waiving the 30-day operative delay, the Commission has considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[13] *See* Release No. 34–58335, *supra* note 3.

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58376; File No. SR–NYSEArca–2008–70]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Amending NYSE Arca Equities Rule 5.2(j)(6)(B)(I), the Generic Listing Standard for Equity Index-Linked Securities

August 18, 2008.

I. Introduction

On June 27, 2008, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange''), through its wholly owned subsidiary, NYSE Arca Equities, Inc. (''NYSE Arca Equities''), filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

(''Act'')[1] and Rule 19b–4 thereunder,[2] a proposal to amend NYSE Arca Equities Rule 5.2(j)(6)(B)(I), the Exchange's generic listing standard for equity index-linked securities (''Equity Index-Linked Securities'') to: (1) Eliminate initial and continued listing capitalization weighted and modified capitalization weighted index requirements; and (2) to adjust certain equity index weighting criteria and adopt notional volume traded per month to both initial listing standards and continued listing standards. The proposed rule change was published for comment in the **Federal Register** on July 17, 2008.[3] The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

NYSE Arca proposes to amend NYSE Arca Equities Rule 5.2(j)(6)(B)(I), the Exchange's generic listing standard for Equity Index-Linked Securities to: (1) Eliminate initial and continued listing capitalization weighted and modified capitalization weighted index requirements; and (2) to adjust certain equity index weighting criteria and adopt notional volume traded per month to both the initial listing standards and continued listing standards.

The Exchange proposes that capitalization weighted index or modified capitalization weighted indexes comply with the initial and continued listing requirements currently applicable to all other equity indexes under NYSE Arca Equities Rule 5.2(j)(6)(B)(I) regardless of the index methodology.

For Equity Index-Linked Securities, the Exchange proposes to eliminate NYSE Arca Equities Rule 5.2(j)(6)(B)(I)(1)(b)(iii), the current initial listing requirement that, in the case of a capitalization weighted index or modified capitalization weighted index, the lesser of the five highest dollar weighted component securities in the index or the highest dollar weighted component securities in the index that in the aggregate represent at least 30% of the total number of component securities in the index, must have an average monthly trading volume of at least 2,000,000 shares over the previous six months. The Exchange also proposes to eliminate NYSE Arca Equities Rule 5.2(j)(6)(B)(I)(2)(a)(iii), the current continued listing requirement, that in the case of a capitalization weighted index or modified capitalization weighted index, the lesser of the five highest dollar weighted component securities in the index or the highest dollar weighted component securities in the index that in the aggregate represent at least 30% of the total number of stocks in the index have an average monthly trading volume of at least 1,000,000 shares over the previous six months.

The Exchange is also proposing to: (i) Remove the requirement that each of the lowest weighted component securities in the index that in the aggregate account for 10% of the weight of the index have trading volume of at least 500,000 shares per month for each of the last six months; and (ii) adopt minimum global notional volume (''Global Notional Volume'')[4] traded per month of $25,000,000 averaged over of the last six months as an option for meeting the listing requirements.

With respect to the continued listing criteria, Rule 5.2(j)(6)(B)(I)(2)(a)(ii) currently sets forth that the trading volume of each component security in the index must be at least 500,000 shares for each of the last six months, except that for each of the lowest weighted components in the index that in the aggregate account for no more than 10% of the weight of the index, trading volume must be at least 400,000 shares for each of the last six months.

The Exchange is proposing to: (i) Remove the requirement that the lowest weighted component securities in the index that in the aggregate accounting for no more than 10% of the weight of the index have trading volume of at least 400,000 shares for each of the last six months; and (ii) adopt minimum Global Notional Volume traded per month of $12,500,000 averaged over the last six months as an option for satisfying the continued listing requirements.

III. Commission's Findings and Order Granting Approval of the Proposed Rule Change

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[5] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[6] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that the Exchange's proposal to eliminate the above-described initial and continued listing requirements for Equity-Index Linked Securities based upon capitalization weighted and modified capitalization weighted indexes would subject all Equity Index-Linked Securities to the same listing requirements, regardless of the methodology upon which a product's underlying index is based. The Commission believes that the proposal should facilitate the listing and trading of Equity Index-Linked Securities with different index methodologies, thus benefiting investors by providing them with a wider selection of derivative products.

The Exchange also proposes to adjust the index weighting criteria in NYSE Arca Equities Rules 5.2(j)(6)(B)(I)(1)(b)(ii) and 5.2(j)(6)(B)(I)(2)(a)(ii) and to adopt an averaged minimum global notional volume traded per month as an option for meeting these initial and continued listing requirements. The Commission believes that focusing the listing requirements on measuring component stocks that in the aggregate account for 90% of the weight of an index should be sufficient to evaluate the liquidity of an index underlying a given Equity-Index Linked Security. The Commission further believes that the use of global notional volume as an alternative measure to global trading volume is acceptable in that it should mitigate the volume discrepancies between low- and high-priced stocks. Finally, the Exchange's proposal to adopt an average of trading or notional volume, as the case may be, should help to eliminate seasonal volume fluctuations that may occur in the trading of an Equity-Index Linked Security in a given month. The Commission believes that the proposal should promote competition and benefit investors, Equity Index-Linked Securities issuers, and third-party index sponsors by expediting the Exchange's ability to list and trade Equity Index-Linked Securities based on a broader group of indexes.

For the foregoing reasons, the Commission believes that the proposed rule change is consistent with the Act.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 58142 (July 11, 2008), 73 FR 41147.

[4] Global Notional Volume is defined as the total shares traded globally times the price per share.

[5] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78f(b)(5).

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[7] that the proposed rule change (SR–NYSEArca–2008–70) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–19474 Filed 8–21–08; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58379; File No. SR–NYSEArca–2008–47]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving Proposed Rule Change To Waive Retroactively as of June 24, 2008, Initial Listing Fees for Companies Who Apply To List Securities Currently Listed on Another National Securities Exchange

August 18, 2008.

I. Introduction

On June 24, 2008, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to waive retroactively as of June 24, 2008, initial listing fees for companies who apply to list securities currently listed on another national securities exchange. The proposed rule change was published in the **Federal Register** on July 14, 2008.[3] The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

The Exchange proposes to waive initial listing fees for companies who apply to list securities currently listed on another national securities exchange. The waiver would apply to all classes of securities. The proposed fee waiver would be applied retroactively to any companies that apply to list after June 24, 2008. The Exchange had previously waived initial listing fees for all companies that transferred from the New York Stock Exchange (''NYSE'') at any time or from Nasdaq Stock Market (''Nasdaq'') or the American Stock Exchange prior to December 31, 2007, or had applied to list prior to that date.[4]

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6(b) of the Act and the rules and regulations thereunder. Specifically, the Commission finds that the proposal is consistent with Sections 6(b)(4)[5] and 6(b)(5) of the Act,[6] which require that an exchange have rules that provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities, and are designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, to protect investors and the public interest, and to not permit unfair discrimination between customers, issuers, brokers, or dealers.[7]

The Commission notes that an issuer seeking to transfer to the Exchange has already paid initial listing fees to another national securities exchange when it became a publicly traded company. In addition, the Commission notes that the Exchange does not expect the loss of initial listing fees to be material and has stated that the fee waiver will not affect the Exchange's commitment of resources to its regulatory oversight of the listing process or its regulatory program. The Exchange would continue to assess annual fees and listing of additional shares fees from these issuers. Further, the Exchange believes that there will be lower burdens associated with its eligibility review of issuers transferring from another national securities exchange. However, the Commission expects, and the Exchange has represented, that a full and independent review of compliance with the listing standards will be conducted for any company seeking to take advantage of the fee waiver, just as for any company that applies for listing on the Exchange. Finally, the Commission also notes that The Nasdaq Stock Market and the New York Stock Exchange have similar provisions.[8] The Commission believes that the proposed waiver could enhance competition among the markets, as the Exchange seeks to become a more attractive listing venue and a viable alternative to listing on other national securities exchanges.

Based on the above, the Commission believes the proposed fee waiver, which is retroactively effective to June 24, 2008, the date of the filing of the proposed rule change,[9] does not constitute an inequitable allocation of reasonable dues, fees, and other charges under Section 6(b)(4) of the Act,[10] does not permit unfair discrimination between issuers under Section 6(b)(5) of the Act,[11] and is otherwise consistent with the requirements of the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[12] that the proposed rule change (SR–NYSEArca–2008–47) is hereby approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–19513 Filed 8–21–08; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58380; File No. SR–Phlx–2008–61]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to Changing Its Name

August 18, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4[2] thereunder, notice is hereby given that on August 15, 2008, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Phlx. The

[7] 15 U.S.C. 78s(b)(2).

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 58109 (July 7, 2008), 73 FR 40415.

[4] *See* Securities Exchange Act Release No. 54007 (June 16, 2006), 71 FR 36155 (June 23, 2006) (SR–PCX–2006–16).

[5] 15 U.S.C. 78f(b)(4).

[6] 15 U.S.C. 78f(b)(5).

[7] In approving this proposed rule change, the Commission notes that it has considered the proposed rules' impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] *See* Nasdaq Rule IM–4500–4 and NYSE Listed Company Manual Section 902.02.

[9] *See supra* note 3.

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to amend its Certificate of Incorporation, By-Laws and Rules to rename itself NASDAQ OMX PHLX, Inc.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.phlx.com/regulatory/reg_rulefilings.aspx*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Phlx included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Phlx has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to rename the Exchange to reflect its new placement within The NASDAQ OMX Group, Inc. corporate structure, following its acquisition by The NASDAQ OMX Group, Inc. on July 24, 2008.[3]

Specifically, all references to the Exchange shall be amended to state ''NASDAQ OMX PHLX, Inc.'' or ''Exchange,'' as appropriate. The Certificate of Incorporation shall be amended to remove all reference to ''Philadelphia Stock Exchange, Inc.'' and replace with ''NASDAQ OMX PHLX, Inc.'' By-Law Article I, Section 1–1(h) shall specifically define the ''Exchange'' as NASDAQ OMX PHLX, Inc. Similarly, a new Rule 1(rr) to be added to the Rules of the Board of Governors shall define the term ''Exchange'' as NASDAQ OMX PHLX, Inc. Further, a new Rule 1(ss) to be added to the Rules of the Board of Governors shall define the terms ''Philadelphia Stock Exchange, Inc.'' and ''Phlx'' as NASDAQ OMX PHLX, Inc.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[4] in general, and furthers the objectives of Section 6(b)(5) of the Act[5] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by renaming the Exchange to reflect its current ownership.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change is concerned solely with the administration of the Exchange pursuant to Section 19(b)(3)(A)(iii) of the Act[6] and Rule 19b–4(f)(3)[7] thereunder. Accordingly, the proposal will take effect upon filing with the Commission. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2008–61 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2008–61. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Phlx. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2008–61 and should be submitted on or before September 12, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–19512 Filed 8–21–08; 8:45 am]

BILLING CODE 8010–01–P

[3] *See* Securities Exchange Act Release Nos. 58179 (July 17, 2008), 73 FR 42874 (July 23, 2008) (SR–Phlx–2008–31); and 58183 (July 17, 2008), 73 FR 42850 (July 23, 2008) (SR–NASDAQ–2008–035).

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(3).

[8] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law (Pub. L.) 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions to OMB-approved information collections and extensions (no change) of existing OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, e-mail, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and the SSA Reports Clearance Officer to the addresses or fax numbers listed below.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, e-mail address: *OIRA_Submission@omb.eop.gov*; (SSA), Social Security Administration, DCBFM, Attn: Reports Clearance Officer, 1333 Annex Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–965–6400, e-mail address: *OPLM.RCO@ssa.gov.*

I. The information collections listed below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. Therefore, your comments would be most helpful if you submit them to SSA within 60 days from the date of this publication. Individuals can obtain copies of the collection instruments by calling the SSA Reports Clearance Officer at 410–965–0454 or by writing to the e-mail address listed above.

1. *Marriage Certification—20 CFR 404.725—0960–0009.* SSA uses Form SSA–3 to collect information to determine if the spouse claimant has the necessary relationship to the number holder (i.e., the worker) to qualify for Old Age, Survivors, and Disability Insurance (OASDI) benefits. The respondents are applicants for spouse's OASDI benefits.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 180,000.

Frequency of Response: 1.

Average Burden per Response: 5 minutes.

Estimated Annual Burden: 15,000 hours.

2. *Letter to Landlord Requesting Rental Information—20 CFR 416.1130(b)—0960–0454.* SSA collects information on Form SSA–L5061 to identify rental subsidy arrangements involving applicants for, and recipients of, Supplemental Security Income (SSI) payments. SSA uses the information to determine an income value for these subsidies, eligibility for payments, and the correct amount payable. The respondents are landlords of SSI claimants.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 49,000.

Frequency of Response: 1.

Average Burden per Response: 10 minutes.

Estimated Annual Burden: 8,167 hours.

3. *Marital Relationship Questionnaire—20 CFR 416.1826—0960–0460.* SSA collects information on Form SSA–4178 to determine, for SSI purposes, whether unrelated individuals of the opposite sex who live together are holding themselves out to the public as husband and wife. SSA needs this information to determine whether we are making correct payments to SSI couples and individuals. The respondents are applicants for and recipients of SSI payments.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 5,100.

Frequency of Response: 1.

Average Burden per Response: 5 minutes.

Estimated Annual Burden: 425 hours.

4. *Report on Individual with Mental Impairment—20 CFR 404.1513 & 416.913—0960–0058.* SSA uses Form SSA–824 to obtain medical evidence from medical sources who have treated the claimant for a mental impairment. SSA uses the information collected on this form to establish whether a claimant filing for disability benefits has a mental impairment that meets the statutory definition of disability in the Social Security Act. The respondents are mental impairment treatment facilities.

Type of Request: Extension of an OMB-approved information collection.

Type of respondents	Number of respondents	Frequency of response	Average burden per response	Total annual burden
Private Sector	25,000	1	36	15,000
State DDSs (State/Local Government)	25,000	1	36	15,000
Totals	50,000			30,000

5. *Record of Supplemental Security Income Inquiry—20 CFR 416.345—0960–0140.* SSA uses the information collected on Form SSA–3462, via telephone or personal interview, to determine potential eligibility for SSI payments and to establish the earliest date of inquiry. The respondents are individuals who inquire about SSI eligibility for themselves or others.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 500,000.

Frequency of Response: 1.

Average Burden per Response: 5 minutes.

Estimated Annual Burden: 41,667 hours.

6. *General Request for Social Security Records—eFOIA—20 CFR 402.130—0960–0716.* SSA uses the information collected on this electronic request for Social Security records to respond to the public's request for information under the Freedom of Information Act (FOIA). SSA also tracks the number and type of requests, fees charged and payment amounts, and whether SSA responds within the required 20 days. Respondents are members of the public including individuals, institutions, or agencies requesting information/documents under FOIA.

Type of Request: Revision of an OMB-approved information collection.

Number of Respondents: 5,000.

Frequency of Response: 1.

Average Burden per Response: 3 minutes.

Estimated Annual Burden: 250 hours.

II. SSA has submitted the information collections listed below. Your

comments on the information collections will be most useful if OMB and SSA receive them within 30 days from the date of this publication. You can request a copy of the information collections by e-mail, *OPLM.RCO@ssa.gov,* fax 410–965–6400, or by calling the SSA Reports Clearance Officer at 410–965–0454.

1. *Supplemental Security Income (SSI)—Quality Review Case Analysis—0960–0133.* Section 1631(e)(1)(B) of the Social Security Act provides that eligibility for SSI payments will not be determined solely on the declarations of the applicant. This section further provides that SSA will collect additional information as necessary to assure correct eligibility and payment amount. To comply with the law, SSA conducts periodic quality review case analysis to assess the SSI program and payment accuracy. SSA uses Form SSA–8508 to collect information on operating efficiency, quality of underlying policies, and the effect of incorrect payments. SSA also uses the data to determine a Federal payment accuracy rate, which is a performance measure for the agency's service delivery goals. Respondents are recipients of SSI payments.

Type of Request: Revision of an OMB approved information collection.

Number of Respondents: 4,500.

Frequency of Response: 1.

Average Burden per Response: 60 minutes.

Estimated Annual Burden: 4,500 hours.

2. *Ticket to Work and Self-Sufficiency Program—20 CFR 411—0960–0644.* The Ticket to Work and Self-Sufficiency Program allows individuals with disabilities who receive Social Security Disability Insurance benefits and SSI payments to work toward decreased dependence on Government cash benefits programs without jeopardizing their benefits during the transition period to employment. Disability payment recipients choose a service provider who will guide them in obtaining, regaining, and maintaining self-supporting employment. 20 CFR 411.140–.730 of the Code of Federal Regulations discusses the regulations governing this program. We show the multiple categories of information collection requirements in these regulations in the chart below. The respondents are individuals entitled to Social Security benefits based on disability, individuals receiving SSI, program managers, employee network (EN) contractors, and State vocational rehabilitation (VR) agencies.

Type of Request: Revision of an OMB approved information collection.

Sections	Section titles	Annual number of responses	Frequency of response	Average burden of response (minutes)	Estimated annual burden (hours)
411.140(d)(3), 411.150(b)(3), 411.325(a).	Individual Work Plans for Non-State EN Tickets.	3,983	1	240	15,932
SSA–1365: 411.140(d)(3), 411.385(a) 411.390.	State VR Agency Ticket Assignments/Reassignments.	25,174	1	3	1,259
411.170(b), 411.385(a), 411.390	Electronic Data Sharing for State VR Agency's Tickets Under Cost Reimbursement.	35,584	1	5	2,965
411.145, 411.325	Requesting Ticket Unassignments ..	2,532	1	15	633
411.535(a)(1)(iii)	Notifying VR Case Closures	8,505	1	5	709
411.192(b)&(c)	Tracking Progress—Request to Place Ticket in Inactive Status.	1,000	1	30	500
411.200(b): SSA–1375, Paper Version (Beneficiaries).	Tracking Progress—Request for Certification of Work and Educational Progress (Individuals).	13,500	1	15	3,375
411.200(b): SSA–1375 Internet Version (State ENs).	Tracking Progress—Request for Certification of Work and Educational Progress (State EN's).	13,500	1	8	1,800
411.210(b)	Request to Reenter Ticket-Use Status after Not Making Timely Progress.	3,145	1	30	1,573
411.365, 411.505, 411.515	Selecting a Payment Plan	118	1	30	59
411.325(d), 411.415	Reporting Referral Agreement Activity (Private Sector).	48	1	480	384
411.575	Requesting EN Payments	12,420	1	60	12,420
411.325(f)	Periodic Outcomes Reporting	2,470	1	120	4,940
411.435, 411.615, 411.635	Dispute Resolutions	2	1	120	4
Totals	.....	121,981	.....	.....	46,553

3. *Youth Transition Process Demonstration Evaluation Data Collection—0960–0687.*

Background

The purpose of the Youth Transition Demonstration (YTD) project is to help young people with disabilities make the transition from school to work. While participating in the project, youth can continue to work and/or continue their education because SSA waives certain disability program rules and offers services to youth who are receiving disability benefits or have a high probability of receiving them. We will fully implement YTD projects in 10 sites across the country. As part of the project, we will conduct an evaluation that will produce empirical evidence on the effects of the waivers and project services including educational attainment, employment, earnings, and receipt of benefits by youth with disabilities, but also on the Social Security Trust Fund and Federal income tax revenues. This type of project is authorized by Sections 1110 and 234 of the Social Security Act.

Project Description

Given the importance of estimating YTD effects as accurately as possible, we will evaluate the project using rigorous analytic methods based on randomly assigning youth to a treatment

or control group. We will conduct several data collections. These include: (1) Baseline interviews with youth and their parents or guardians prior to random assignment; (2) followup interviews at 12 and 36 months after random assignment; (3) interviews and/or roundtable discussions with local program administrators, program supervisors, and service delivery staff; and (4) focus groups of youths, their parents, and service providers. The respondents are youths with disabilities enrolled in the project; their parents or guardians; program staff; and service providers.

Type of Request: Revision of an existing OMB Clearance.

Data collection year and collection	Number of respondents	Responses per respondent	Average burden per response (hours)	Total response burden (hours)
2008:				
Baseline	2,531	1	0.55	1,392
Informed Consent	2,531	1	.083	210
12 month follow-up	1,502	1	0.83	1,247
In-depth interviews	120	1	.42	50
Focus group	60	1	1.5	90
Program staff/service provider	32	1	1	32
Total 2008		6776		3,021

4. *Waiver of Supplemental Security Income Payment Continuation—20 CFR 416.1400–416.1422—0960—NEW.* An SSI claimant receiving payment during the appeals process has the option of waiving or stopping the payments until a decision is made on their claim. The claimant uses Form SSA–263–U2 to make the request. SSA uses the information on this form as proof that the individual does not want to continue to receive payments until a decision is made on their appeal and that they understand their due process rights. The respondents are SSI recipients.

Type of Request: Existing Information Collection in Use without an OMB Number.

Number of Respondents: 3,000.

Frequency of Response: 1.

Average Burden per Response: 5 minutes.

Estimated Annual Burden: 250 hours.

Dated: August 18, 2008.

Elizabeth A. Davidson,

Reports Clearance Officer, Social Security Administration.

[FR Doc. E8–19510 Filed 8–21–08; 8:45 am]

BILLING CODE 4191–02–P

SUSQUEHANNA RIVER BASIN COMMISSION

Notice of Public Hearing and Commission Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice of Public Hearing and Commission Meeting.

SUMMARY: The Susquehanna River Basin Commission will hold a public hearing as part of its regular business meeting beginning at 1 p.m. on September 11, 2008, in Lewisburg, Pa. At the public hearing, the Commission will consider: (1) Approval of certain water resources projects; (2) enforcement actions for six projects; and (3) a request for extension of an emergency certificate issued on July 24, 2008. Details concerning the matters to be addressed at the public hearing and business meeting are contained in the Supplementary Information section of this notice.

DATES: September 11, 2008.

ADDRESSES: Bucknell University—Elaine Langone Center, Center Room, Lewisburg, Pa. See Supplementary Information section for mailing and electronic mailing addresses for submission of written comments.

FOR FURTHER INFORMATION CONTACT: Richard A. Cairo, General Counsel, telephone: (717) 238–0423, ext. 306; fax: (717) 238–2436; e-mail: *rcairo@srbc.net* or Stephanie L. Richardson, Executive Assistant, telephone: (717) 238–0423, ext. 304; fax: (717) 238–2436; e-mail: *srichardson@srbc.net.*

SUPPLEMENTARY INFORMATION: In addition to the public hearing and its related action items identified below, the business meeting also includes the following items on the agenda: (1) A special presentation on Bucknell University's Susquehanna River Initiative by Dr. Benjamin Hayes, (2) a special presentation on Environmental Flows by Mark Breyer of the Nature Conservancy, (3) a report on the present hydrologic conditions of the basin, (4) consideration of a health insurance trust fund, (5) approval/ratification of various grants and contracts, (6) consideration of a proposed rulemaking action regarding consumptive use by gas well development projects, (7) establishment of a ''Compliance Reserve Fund'' to hold the proceeds of settlements and civil penalty assessments, (8) adoption of an errata sheet to the March 13, 2008, public hearing transcript, (9) discussion of the funding status of the basin streamgage network, (10) appointment of a new Secretary to the Commission; and (11) adoption of a 2009 Commission meeting schedule. The Commission will also hear a Legal Counsel's report.

Public Hearing—Projects Scheduled for Action

1. Project Sponsor and Facility: East Resources, Inc. (Seeley Creek), Town of Southport, Chemung County, N.Y. Application for surface water withdrawal of up to 0.036 mgd.

2. Project Sponsor and Facility: Chesapeake Appalachia, LLC (for operations in Chemung and Tioga Counties, N.Y., and Bradford, Susquehanna, and Wyoming Counties, Pa.). Application for consumptive water use of up to 2.075 mgd from various surface water sources and the following public water suppliers: Towanda Municipal Authority, Aqua Pennsylvania, Inc.—Susquehanna Division, Canton Borough Authority, Borough of Troy, and Village of Horseheads, N.Y.

3. Project Sponsor and Facility: Chesapeake Appalachia, LLC (Susquehanna River), Town of Owego, Tioga County, N.Y. Application for surface water withdrawal of up to 0.999 mgd.

4. Project Sponsor and Facility: Cabot Oil & Gas Corporation (for operations in Susquehanna and Wyoming Counties, Pa.). Application for consumptive water use of up to 3.039 mgd from various surface water sources and the following public water suppliers: Tunkhannock Borough Municipal Authority, Pennsylvania American Water Company—Montrose System, and Meshoppen Borough Council.

5. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Susquehanna

River), Great Bend Borough, Susquehanna County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

6. Project Sponsor and Facility: Chesapeake Appalachia, LLC (Susquehanna River), Athens Township, Bradford County, Pa. Application for surface water withdrawal of up to 0.999 mgd.

7. Project Sponsor and Facility: Chesapeake Appalachia, LLC (Susquehanna River), Oakland Township, Susquehanna County, Pa. Application for surface water withdrawal of up to 0.999 mgd.

8. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Susquehanna River), Susquehanna Depot Borough, Susquehanna County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

9. Project Sponsor and Facility: Fortuna Energy Inc. (Susquehanna River), Sheshequin Township, Bradford County, Pa. Application for surface water withdrawal of up to 0.250 mgd.

10. Project Sponsor and Facility: East Resources, Inc. (Crooked Creek), Middlebury Township, Tioga County, Pa. Application for surface water withdrawal of up to 0.036 mgd.

11. Project Sponsor and Facility: Chief Oil & Gas, LLC (for operations in Bradford County, Pa.). Application for consumptive use of water of up to 5.000 mgd.

12. Project Sponsor and Facility: Chief Oil & Gas, LLC (Sugar Creek), West Burlington Township, Bradford County, Pa. Application for surface water withdrawal of up to 0.053 mgd.

13. Project Sponsor and Facility: Fortuna Energy Inc. (Sugar Creek), West Burlington Township, Bradford County, Pa. Application for surface water withdrawal of up to 0.250 mgd.

14. Project Sponsor and Facility: Chesapeake Appalachia, LLC (Susquehanna River), Wysox Township, Bradford County, Pa. Application for surface water withdrawal of up to 0.999 mgd.

15. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Unnamed Tributary to Meshoppen Creek), Dimock Township, Susquehanna County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

16. Project Sponsor and Facility: Fortuna Energy Inc. (Towanda Creek), Franklin Township, Bradford County, Pa. Application for surface water withdrawal of up to 0.250 mgd.

17. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Martins Creek), Lathrop Township, Susquehanna County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

18. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Tunkhannock Creek), Lennox Township, Susquehanna County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

19. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Meshoppen Creek-2), Lemon Township, Wyoming County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

20. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Meshoppen Creek-1), Lemon Township, Wyoming County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

21. Project Sponsor and Facility: Pennsylvania General Energy Company, LLC (operations in Potter and McKean Counties, Pa.). Application for consumptive water use of up to 4.900 mgd from various surface water sources and the following public water suppliers: Jersey Shore Joint Water Authority, Williamsport Municipal Water Authority, and Borough of Montoursville.

22. Project Sponsor and Facility: Pennsylvania General Energy Company, LLC (East Fork Sinnemahoning Creek—Horton), East Fork Township, Potter County, Pa. Application for surface water withdrawal of up to 0.008 mgd.

23. Project Sponsor and Facility: Chesapeake Appalachia, LLC (Susquehanna River), Mehoopany Township, Wyoming County, Pa. Application for surface water withdrawal of up to 0.999 mgd.

24. Project Sponsor and Facility: Pennsylvania General Energy Company, LLC (First Fork Sinnemahoning Creek), Sylvania Township, Potter County, Pa. Application for surface water withdrawal of up to 0.107 mgd.

25. Project Sponsor and Facility: Pennsylvania General Energy Company, LLC (East Fork Sinnemahoning Creek—East Fork), East Fork Township, Potter County, Pa. Application for surface water withdrawal of up to 0.025 mgd.

26. Project Sponsor and Facility: Pennsylvania General Energy Company, LLC (East Fork Sinnemahoning Creek), Wharton Township, Potter County, Pa. Application for surface water withdrawal of up to 0.027 mgd.

27. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Susquehanna River), Tunkhannock Township, Wyoming County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

28. Project Sponsor and Facility: Pennsylvania General Energy Company, LLC (First Fork Sinnemahoning Creek), Wharton Township, Potter County, Pa. Application for surface water withdrawal of up to 0.231 mgd.

29. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Bowmans Creek), Eaton Township, Wyoming County, Pa. Application for surface water withdrawal of up to 0.980 mgd.

30. Project Sponsor and Facility: Neptune Industries, Inc. (Lackawanna River), Borough of Archbald, Lackawanna County, Pa. Application for surface water withdrawal of up to 0.499 mgd.

31. Project Sponsor and Facility: PEI Power Corporation, Borough of Archbald, Lackawanna County, Pa. Modification to consumptive water use and surface water withdrawal approval (Docket No. 20010406) for addition of up to 0.530 mgd from a public water supplier as a secondary supply source, and settlement of an outstanding compliance matter.

32. Project Sponsor and Facility: Range Resources—Appalachia, LLC (for operations in Bradford, Centre, Clinton, Lycoming, Sullivan, and Tioga Counties, Pa.). Application for consumptive water use of up to 5.000 mgd from various surface water sources and the following public water suppliers: Jersey Shore Joint Water Authority—Pine Creek and Anthony Facilities, Williamsport Municipal Water Authority, City of Lock Haven Water Department, Borough of Bellefonte, Borough of Montoursville, Milesburg Water System, and Towanda Municipal Authority.

33. Project Sponsor and Facility: Range Resources—Appalachia, LLC (Lycoming Creek), Lewis Township, Lycoming County, Pa. Application for surface water withdrawal of up to 0.200 mgd.

34. Project Sponsor and Facility: Range Resources—Appalachia, LLC (Lycoming Creek), Lycoming Township, Lycoming County, Pa. Application for surface water withdrawal of up to 0.200 mgd.

35. Project Sponsor and Facility: Chief Oil & Gas, LLC (for operations in Lycoming County, Pa.) Application for consumptive water use of up to 5.000 mgd from various surface water sources and the following public water suppliers: Jersey Shore Joint Water Authority—Pine Creek and Anthony Facilities, Williamsport Municipal Water Authority, Borough of Montoursville, and Towanda Municipal Authority.

36. Project Sponsor and Facility: Chief Oil & Gas, LLC (Muncy Creek), Penn Township, Lycoming County, Pa.

Application for surface water withdrawal of up to 0.099 mgd.

37. Project Sponsor and Facility: Chief Oil & Gas, LLC (Larrys Creek), Mifflin Township, Lycoming County, Pa. Application for surface water withdrawal of up to 0.099 mgd.

38. Project Sponsor and Facility: Chief Oil & Gas, LLC (Pine Creek), Cummings Township, Lycoming County, Pa. Application for surface water withdrawal of up to 0.099 mgd.

39. Project Sponsor and Facility: Chief Oil & Gas, LLC (Muncy Creek), Picture Rocks Borough, Lycoming County, Pa. Application for surface water withdrawal of up to 0.099 mgd.

40. Project Sponsor and Facility: Chief Oil & Gas, LLC (Loyalsock Creek), Montoursville Borough, Lycoming County, Pa. Application for surface water withdrawal of up to 0.099 mgd.

41. Project Sponsor and Facility: Range Resources—Appalachia, LLC (West Branch Susquehanna River), Colebrook Township, Lycoming County, Pa. Application for surface water withdrawal of up to 0.200 mgd.

42. Project Sponsor and Facility: Rex Energy Corporation (for operations in Centre and Clearfield Counties, Pa.). Application for consumptive water use of up to 5.000 mgd from various surface water sources and the following public water supplier: Clearfield Municipal Authority.

43. Project Sponsor and Facility: Rex Energy Corporation (Upper Little Surveyor Run), Girard Township, Clearfield County, Pa. Application for surface water withdrawal of up to 0.400 mgd.

44. Project Sponsor and Facility: Rex Energy Corporation (Lower Little Surveyor Run), Girard Township, Clearfield County, Pa. Application for surface water withdrawal of up to 0.400 mgd.

45. Project Sponsor and Facility: Rex Energy Corporation (West Branch Susquehanna River), Goshen Township, Clearfield County, Pa. Application for surface water withdrawal of up to 5.000 mgd.

46. Project Sponsor and Facility: Range Resources—Appalachia, LLC (Beech Creek), Snow Shoe Township, Centre County, Pa. Application for surface water withdrawal of up to 0.200 mgd.

47. Project Sponsor and Facility: Rex Energy Corporation (Moshannon Creek—Route 53), Snow Shoe Township, Centre County, Pa. Application for surface water withdrawal of up to 2.000 mgd.

48. Project Sponsor and Facility: Rex Energy Corporation (Moshannon Creek Outfall), Snow Shoe Township, Centre County, Pa. Application for surface water withdrawal of up to 2.000 mgd.

49. Project Sponsor and Facility: Rex Energy Corporation (Moshannon Creek—Peale), Snow Shoe Township, Centre County, Pa. Application for surface water withdrawal of up to 2.000 mgd.

50. Project Sponsor: Suez Energy North America, Inc. Project Facility: Viking Energy of Northumberland, Point Township, Northumberland County, Pa. Modification to consumptive water use approval (Docket No. 19870301).

51. Project Sponsor: New Enterprise Stone & Lime Co., Inc. Project Facility: Tyrone Quarry, Warriors Mark Township, Huntingdon County, and Snyder Township, Blair County, Pa. Modification to consumptive water use and groundwater withdrawal approval (Docket No. 20031205) for groundwater withdrawals of 0.095 mgd from Well 1, 0.006 mgd from Well 2, and 0.050 mgd from Well 3, and 0.003 mgd from Well 5.

52. Project Sponsor and Facility: Papetti's Hygrade Egg Products, Inc., d.b.a. Michael Foods Egg Products Co., Upper Mahantango Township, Schuylkill County, Pa. Modification of consumptive water use approval (Docket No. 19990903) and a new groundwater withdrawal of 0.450 mgd from Well 3.

53. Project Sponsor: Old Castle Materials, Inc. Project Facility: Pennsy Supply, Inc.—Hummelstown Quarry, South Hanover Township, Dauphin County, Pa. Application for surface water withdrawal of up to 29.952 mgd.

54. Project Sponsor and Facility: Dart Container Corporation of Pennsylvania, Upper Leacock Township, Lancaster County, Pa. Modification of groundwater approval (Docket No. 20040910).

55. Project Sponsor: East Berlin Area Joint Authority. Project Facility: Buttercup Farms, Hamilton Township, Adams County, Pa. Applications for groundwater withdrawals (30-day averages) of 0.144 mgd from Well TW–1, 0.029 mgd from Well TW–2, and a total system withdrawal limit of 0.173 mgd.

56. Project Sponsor: Project Sponsor: PPL Holtwood, LLC. Project Facility: Holtwood Hydroelectric Station, Martic and Conestoga Townships, Lancaster County, and Chanceford and Lower Chanceford Townships, York County, Pa. Applications for amendment to existing FERC license (FERC Project No. 1881) and for redevelopment of the project with modification of its operations on the lower Susquehanna River, including the addition of a second power station and associated infrastructure.

Public Hearing—Projects Scheduled for Enforcement Action

1. Project Sponsor and Facility: Cabot Oil & Gas Corporation; Teel, Greenwood, Ely, Lewis and Black Wells; Dimock and Springfield Townships, Susquehanna County, Pa.

2. Project Sponsor and Facility: Chief Oil & Gas, LLC; Kensinger, Spotts, and Poor Shot Wells; Mifflin, Penn and Anthony Townships, Lycoming County, Pa.

3. Project Sponsor and Facility: EOG Resources, Inc.; Houseknecht, Olsyn and Pierce Wells; Springfield Township, Bradford County, Pa.; PHC Well, Lawrence Township, Clearfield County, Pa.; Leasgang and Pichler Wells, Jay Township, Elk County, Pa.

4. Project Sponsor and Facility: North Coast Energy, Inc.; Litke Wells, Burnside Township, Centre County, Pa.

5. Project Sponsor and Facility: Range Resources—Appalachia LLC; McWilliams, Bobst Mountain, Ogontz, and Ulmer Wells; Cogan House, Cummings and Lycoming Townships, Lycoming County, Pa.; Gulf USA Well, Snow Shoe Township, Centre County, Pa.; Duffey Well, Ridgebury Township, Bradford County, Pa.

6. Project Sponsor and Facility: Turm Oil, Inc., LaRue Well, Rush Township, Susquehanna County, Pa.

Public Hearing—Request to Extend Emergency Certificate

1. CAN DO, Inc., Hazle Township, Luzerne County, Pa.—Request to extend the use of Site 14 Test Well to serve Humbolt Industrial Park.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.*, 18 CFR Parts 806, 807, and 808.

Dated: August 12, 2008.

Paul O. Swartz,

Executive Director.

[FR Doc. E8–19492 Filed 8–21–08; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2008–36]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief

from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before September 11, 2008.

ADDRESSES: You may send comments identified by Docket Number FAA–2008–0826 using any of the following methods:

- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- Fax: Fax comments to the Docket Management Facility at 202–493–2251.
- Hand Delivery: Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kenna Sinclair (425) 227–1556, Transport Airplane Directorate, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SE, Renton, WA 98055–4056; or Fran Shaver (202) 267–9681, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 18, 2008.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2008–0826.
Petitioner: The Boeing Company.
Sections of 14 CFR Affected: §§ 25.841(a)(2) and 25.841(a)(3).
Description of Relief Sought: The petitioner is requesting an exemption from certain pressurized cabin requirements in regard to uncontained engine failure for Boeing Model 747–8/8F series airplanes.

[FR Doc. E8–19461 Filed 8–21–08; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2008–38]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATE: Comments on this petition must identify the petition docket number involved and must be received on or before September 2, 2008.

ADDRESSES: You may send comments identified by Docket Number FAA–2008–0905 using any of the following methods:

- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- Fax: Fax comments to the Docket Management Facility at 202–493–2251.
- Hand Delivery: Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jan Thor (425) 227–2127, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, or Frances Shaver (202) 267–9681, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 19, 2008.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2008–0905.

Petitioner: Aviation Partners Boeing.

Section of 14 CFR Affected: § 25.981(a)(3).

Description of Relief Sought: Aviation Partners Boeing requests exemption from the lightning protection requirements for wing fasteners on the installation of blended winglets on their Boeing Model 767–300/300F airplanes.

[FR Doc. E8–19477 Filed 8–21–08; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2008–0118]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under Supplementary Information. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on July 19, 2007. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by September 22, 2008.

ADDRESSES: You may submit comments identified by DOT DMS Docket Number FHWA–2007–28755 by any of the following methods:

Web Site: http://dms.dot.gov. Follow the instructions for submitting comments on the DOT electronic docket site.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Hand Delivery: U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Serena Matthews-Parrish, 202–366–1201, Office of Human Resources, Student Outreach and Career Entry Programs Group, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 7:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Summer Transportation Internship Program for Diverse Groups (STIPDG).

Background: STIPDG is authorized by The Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU), Section 5204–Training and Education/Surface Transportation Workforce Development, Training, and Education Act. Section 5204 states that subject to project approval by the Secretary, a State may obligate funds apportioned to the State for primary core programs workforce development, training, and education, including student internships; university or community college support; and outreach to develop interest and promote participation in surface transportation careers. STIPDG is an important part of DOT's intermodal effort to promote the entry of women, persons with disabilities, and members of diverse groups into transportation careers where traditionally these groups have been under-represented. Accordingly, FHWA's Office of Civil Rights will continue to actively support the STIPDG by working closely with FHWA's Office of Human Resources, Student Outreach and Career Entry Programs Group, which has responsibility for administering the program. The program includes participation and placement of college students into summer intern placement nationwide, for all the DOT operating administrations. FHWA implements the program via a contractor that is selected through open competition. The STIPDG accepts approximately 500 applications each year, placing as few as 70 and as many as 100 undergraduate, graduate, and law students in transportation-related, non-administrative, technical, hands-on assignments with a Federal and State mentor providing on-the-job training. The STIPDG provides college students with an opportunity to work on current transportation-related topics and issues identified in or directly pertaining to the current DOT Strategic Plan. The STIPDG is open to all qualified applicants regardless of race, color, religion, sex, national origin, political affiliation, sexual orientation, marital status, disability, age, membership in an employee organization, or other non-merit factor. The STIPDG is open to all applicants based on the following eligibility requirements. Applicants must be currently enrolled in degree-granting programs of study at accredited U.S. institutions of higher education recognized by the U.S. Department of Education. Undergraduate applicants must be juniors or seniors for the fall of 2008. Undergraduate applicants from Junior, Tribal, or Community Colleges must have completed their first year. Law applicants must be entering their second or third year of law school in the fall of 2009. Applicants who are scheduled to graduate during the coming spring or summer semesters are not eligible for consideration for the STIPDG unless: (1) They have been accepted for graduate school enrollment; (2) they have been accepted for enrollment at an institution of higher education; or (3) their acceptance is pending. In all instances, the applicant must submit their completed application packages and documentation (with the school's logo) reflecting their status. Former STIPDG interns may apply but will not receive preferential consideration. Applicants will be evaluated based on the completeness of the application and the required documents listed below. Priority will be given to those with GPA's of 3.0 or better (for the Major and/or cumulatively). Applicants must be available and able to participate in the entire 10-week program.

Respondents: Approximately 500 applicants.

Frequency: Student applies every fall by going to the STIPDG Web site at: *http://www.fhwa.dot.gov/education/Stipdg.htm,* reading the requirements, retrieving the necessary 1-page forms, completing them, and packaging and forwarding all required documents to the designated PO Box identified on the Web site. Applications are received during the fall, with student offer letters sent by the spring, and placement offered by the first week of June for the majority of participants. The summer internship is managed by a contractor who responds to each applicant within 24 hours of receipt of the application, confirms via e-mail notification to the applicant whether or not the application package is received and deemed completed; and within 90 days notifies the applicant regarding the status of acceptance into the program. The required STIPDG Application documents include:

- The actual 1-page STIPDG Application.
- A copy of the most recent Transcript/Grade Record/Report.
- At least one reference (if possible with comments) from a department chair, professor, advisor, employer using the attached 1-page Reference Form.
- A current 1-page resume reflecting work experience, volunteerism, awards, leadership, and extra curricular activities.

• The actual 1-page, 2009 Applicant's Area of Interest/Geographical Preference Sheet, also included on this site.

• For Undergraduate Students: A typed essay, 1-page, double-spaced, minimum 12-point type, on your transportation interests, describing how participation in the 2009 STIPDG will enhance educational and career plans and goals.

• For Graduate Students: A writing sample representing your educational and career plans and goals.

• For Law Students: A legal writing sample.

Estimated Average Burden per Response: The estimated average burden is 4 hours per respondent.

Estimated Total Annual Burden Hours: The estimated total annual burden is 2,000 hours per year.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: August 14, 2008.

James R. Kabel,

Chief, Management Programs and Analysis Division.

[FR Doc. E8–19326 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Over-the-Road Bus Accessibility Program Announcement of Project Selections

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of Project Selections.

SUMMARY: The U.S. Department of Transportation (DOT) Federal Transit Administration (FTA) announces the selection of projects to be funded under Fiscal Year (FY) 2007 and FY 2008 appropriations for the Over-the-Road Bus (OTRB) Accessibility Program, authorized by section 3038 of the Transportation Equity Act for the 21st Century (TEA–21). The OTRB Accessibility Program makes funds available to private operators of over-the-road buses to help finance the incremental capital and training costs of complying with DOT's Over-the-Road Bus accessibility rule.

FOR FURTHER INFORMATION CONTACT: The appropriate FTA Regional Office for grant-specific issues (Appendix A); or Blenda Younger, Office of Program Management, 202–366–2053, for general information about the OTRB Program.

SUPPLEMENTARY INFORMATION:

A total of $15.9 million, which includes $7.6 million in FY 2007 funds and $8.3 million in FY 2008 funds is available for allocation. Of the FY 2007 funds, $5.7 million is available to be awarded to intercity fixed-route providers and $1.9 million is available for other providers. Also, of the FY 2008 funds, $6.225 million is available to be awarded to intercity fixed-route providers and $2.075 million is available for other providers. The category of other providers includes commuter, charter, and tour bus operators.

A total of 123 applicants requested $41.6 million: $21.8 million was requested by intercity fixed-route providers, and $19.8 million was requested by all other providers. Project selections were made on a discretionary basis, based on each applicant's responsiveness to statutory project selection criteria, fleet size, and level of funding received in previous years. Because of the high demand for the funds available, most successful applicants received less funding than they requested, and applicants who did not meet the statutory criteria were not selected for funding. Selected projects will result in the addition of lifts to 375 new vehicles, the retrofitting of 96 vehicles, and $136,915 for training in the proper operation of the equipment. Each of the following 79 awardees listed in Table 1, as well as the 44 applicants who were not selected for funding, will receive a letter that explains how funding decisions were made.

Eligible project costs may be incurred by awardees prior to final grant approval. The incremental capital cost for adding wheelchair lift equipment to any new vehicles delivered on or after June 9, 1998, the effective date of TEA–21, is eligible for funding under the OTRB Accessibility Program. Applicants selected for funding may be contacted by FTA regional offices if additional information is needed before grants are made. Awards are processed through FTA's electronic grants management system, TEAM–WEB, and the project identification (ID) listed will be used to track the obligation of funds for the projects selected. The grant applications will be sent to the U.S. Department of Labor (DOL) for certification under labor protection requirements pursuant to 49 U.S.C. 5333(b). After referring applications to affected employees represented by a labor organization, DOL will issue a certification to FTA. Terms and conditions of the certification will be incorporated in the FTA grant agreement under the new guidelines replacing those in 29 CFR part 215. Please see Amendment to Section 5333(b), Guidelines to Carry Out New Programs Authorized by the Transportation Equity Act for the 21st Century (TEA–21); Final Rule (64 FR 40990, July 28, 1999).

Issued in Washington, DC, this 15th day of August, 2008.

James S. Simpson,

Administrator.

Appendix A

Richard H. Doyle: Regional Administrator, Region 1—Boston, Kendall Square, 55 Broadway, Suite 920, Cambridge, MA 02142–1093. Tel. 617–494–2055. States served: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.	Robert C. Patrick: Regional Administrator, Region 6—Ft. Worth, 819 Taylor Street, Room 8A36, Ft. Worth, TX 76102. Tel. 817–978–0550. States served: Arkansas, Louisiana, Oklahoma, New Mexico and Texas.
Brigid Hynes-Cherin, Regional Administrator, Region 2—New York, One Bowling Green, Room 429, New York, NY 10004–1415. Tel. No. 212–668–2170. States served: New Jersey, New York.	Mokhtee Ahmad, Regional Administrator, Region 7—Kansas City, MO, 901 Locust Street, Room 404, Kansas City, MO 64106. Tel. 816–329–3920. States served: Iowa, Kansas, Missouri, and Nebraska.

Letitia Thompson, Regional Administrator, Region 3—Philadelphia, 1760 Market Street, Suite 500, Philadelphia, PA 19103–4124. Tel. 215–656–7100. States served: Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and District of Columbia.	Terry Rosapep, Regional Administrator, Region 8—Denver, 12300 West Dakota Ave., Suite 310, Lakewood, CO 80228–2583. Tel. 720–963–3300. States served: Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming.
Yvette Taylor, Regional Administrator, Region 4—Atlanta, 230 Peachtree Street, NW., Suite 800, Atlanta, GA 30303. Tel. 404–865–5600. States served: Alabama, Florida, Georgia, Kentucky, Mississippi, Islands.	Leslie T. Rogers, Regional Administrator, Region 9—San Francisco, 201 Mission Street, Room 1650, San Francisco, CA 94105–1926. Tel. 415–744–3133. States served: American Samoa, Arizona, California, Guam, Hawaii, Nevada, and the Northern Mariana Islands.
Marisol Simon, Regional Administrator, Region 5—Chicago, 200 West Adams Street, Suite 320, Chicago, IL 60606. Tel. 313–353–2789. States served: Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.	Rick Krochalis, Regional Administrator, Region 10—Seattle, Jackson Federal Building, 915 Second Avenue, Suite 3142, Seattle, WA 98174–1002. Tel. 206–220–7954. States served: Alaska, Idaho, Oregon, and Washington.

BILLING CODE 4910–57–P

Table 1

AWARD AMOUNT					
Operator	City/State	Intercity Fixed-Route	Other	Total	Project ID
Region I					
Arrow Line	E. Hartford, CT		$155,550	$155,550	D2007-OTRB-001
Bonanza Bus Lines	Providence, RI	$194,830		$194,830	D2007-OTRB-002
Cavalier Coach Trailways	Boston, MA		$41,000	$41,000	D2007-OTRB-003
C&J Trailways	Portsmouth, NH	$76,600		$76,600	D2007-OTRB-004
Coach Tours, LTD.	Brookfield, CT		$26,100	$26,100	D2007-OTRB-005
Concord Coach Lines	Concord, NH	$48,400		$48,400	D2007-OTRB-006
Dattco, Inc.	New Britain, CT		$30,600	$30,600	D2007-OTRB-007
Flagship Trailways	Johnston, RI		$41,000	$41,000	D2007-OTRB-008
Northeast Charter & Tour Co., Inc.	Lewiston, ME		$41,901	$41,901	D2007-OTRB-009
Peter Pan Bus Lines	Springfield, MA	$378,684		$378,684	D2007-OTRB-010
Plymouth & Brockton	Plymouth, MA	$55,620		$55,620	D2007-OTRB-011
Region II					
Adirondack Trailways	Hurley, NY	$441,000		$441,000	D2007-OTRB-012
Classic Coach	Bohemia, NY	$92,250		$92,250	D2007-OTRB-013
Hampton Jitney, Inc.	Southampton, NY	$89,412		$89,412	D2007-OTRB-014
Paradise Trailways	Hicksville, NY		$44,158	$44,158	D2007-OTRB-015
Southern Tier Stages, Inc.	Endicott, NY		$53,000	$53,000	D2007-OTRB-016
Swartout Coaches, Inc.	Ithaca, NY		$31,080	$31,080	D2007-OTRB-017
Region III					
A P Xpress Bus Company	Capital Heights, MD		$85,980	$85,980	D2007-OTRB-018
Butler Motor Transit	Butler, PA		$89,100	$89,100	D2007-OTRB-019
Capitol Trailways	Harrisburg, PA	$110,565		$110,565	D2007-OTRB-020
Carl R. Bieber, Inc.	Kutztown, PA	$121,624		$121,624	D2007-OTRB-021
David Thomas Tours, Inc.	Philadelphia, PA	$27,200		$27,200	D2007-OTRB-022
First Priority Tours, Inc.	District Heights, MD		$89,550	$89,550	D2007-OTRB-023
Fullington Trailways	Clearfield, PA	$201,800		$201,800	D2007-OTRB-024
Keller Transportation, Inc.	Waldorf, MD	$470,496		$470,496	D2007-OTRB-025
Lenzer Coach Lines	Sewickley, PA		$78,686	$78,686	D2007-OTRB-026
Martz Trailways	Wilkes-Barre, PA	$379,672		$379,672	D2007-OTRB-027
R & J Transportation, Inc.	Pottsville, PA		$29,999	$29,999	D2007-OTRB-028
Trans-Bridge Lines	Bethlehem, PA	$93,970		$93,970	D2007-OTRB-029
Region IV					
American Coach Lines of Miami	Miami, FL	$156,200		$156,200	D2007-OTRB-030
Blue Grass Tours, Inc.	Lexington, KY		$24,680	$24,680	D2007-OTRB-031
Discovery Charters, Inc.	Longwood, FL		$27,063	$27,063	D2007-OTRB-032
Endeavor Bus Lines	Miami, FL		$116,562	$116,562	D2007-OTRB-033
First Class Coach Company, Inc.	St. Petersburg, FL	$120,800		$120,800	D2007-OTRB-034
Florida Cruise Connection, Inc.	Sarasota, FL	$104,670		$104,670	D2007-OTRB-035
Majestic Tours	Rock Hill, SC		$46,000	$46,000	D2007-OTRB-036
Midnight Sun Tours, Inc.	Lake Worth, FL		$78,600	$78,600	D2007-OTRB-037
Royal Tours & Trailways, Inc.	Randleman, NC		$40,000	$40,000	D2007-OTRB-038
Region V					
Able Trek Tours, Inc.	Reedsburg, WI		$25,159	$25,159	D2007-OTRB-039
American Heritage Trails, LLC	LaOtto, IN		$30,070	$30,070	D2007-OTRB-040
Colonial Coach Lines, Inc.	Mount Prospect, IL	$403,000		$403,000	D2007-OTRB-041
Compass Coach	Cedar Springs, MI		$23,721	$23,721	D2007-OTRB-042
Dean Charters & Tours, Inc.	Lansing, MI		$139,000	$139,000	D2007-OTRB-043
Indian Trails, Inc.	Owosso, MI		$45,720	$45,720	D2007-OTRB-044
Jefferson Lines	Minneapolis, MN	$238,400		$238,400	D2007-OTRB-045
Keeshin Charter Service	Chicago, IL		$56,000	$56,000	D2007-OTRB-046
Kobussen Buses LTD.	Kaukauna, WI		$28,906	$28,906	D2007-OTRB-047
Lakefront Lines, Inc.	Brook Park, OH	$97,353		$97,353	D2007-OTRB-048
Lamers Bus Lines, Inc.	Green Bay, WI		$82,991	$82,991	D2007-OTRB-049
Megabus USA	Chicago, IL	$420,000		$420,000	D2007-OTRB-050
Miller Transportation	Indianapolis, IN		$41,000	$41,000	D2007-OTRB-051
Pioneer Coach Lines, Inc.	Mount Prospect, IL		$255,000	$255,000	D2007-OTRB-052
Riteway Bus Service, Inc.	Richfield, WI	$86,482		$86,482	D2007-OTRB-053
Thompson Motorcoach	Indianapolis, IN		$143,000	$143,000	D2007-OTRB-054

Table 1

AWARD AMOUNT					
Operator	**City/State**	**Intercity Fixed-Route**	**Other**	**Total**	**Project ID**
Van Galder Bus Company	Janesville, WI	$297,540		$297,540	D2007-OTRB-055
Wisconsin Coach Lines	Waukesha, WI		$108,000	$108,000	D2007-OTRB-056
Region VI					
ACH Travel & Tours, Inc.	Pharr, TX		$75,000	$75,000	D2007-OTRB-057
All Aboard America	Santa Fe, NM		$212,800	$212,800	D2007-OTRB-058
Americanos USA, LLC	Dallas, TX		$264,600	$264,600	D2007-OTRB-059
Calco Travel, Inc.	Geishmar, LA		$183,000	$183,000	D2007-OTRB-060
Crucero USA, LLC	Dallas, TX	$151,200		$151,200	D2007-OTRB-061
Del Valle Grand Turismo, Inc.	Pharr, TX		$74,000	$74,000	D2007-OTRB-062
Eagle Tours, Inc.	Irving, TX		$51,050	$51,050	D2007-OTRB-063
Greyhound Lines, Inc.	Dallas, TX	$6,361,200		$6,361,200	D2007-OTRB-064
Kerrville Bus Co.	San Antonio, TX	$160,650		$160,650	D2007-OTRB-065
Louisiana Coaches, Inc.	Marrero, LA		$41,000	$41,000	D2007-OTRB-066
Sun Travel Trailways	Beaumont, TX		$42,079	$42,079	D2007-OTRB-067
Region VII					
Arrow Stage Lines	Norfolk, NE		$92,250	$92,250	D2007-OTRB-068
Burlington Trailways	W. Burlington, IA	$54,300		$54,300	D2007-OTRB-069
Heartland Trailways	St. Joseph, MO		$58,500	$58,500	D2007-OTRB-070
White Knight Limousine	Columbia, MO		$41,000	$41,000	D2007-OTRB-071
Region VIII					
Powder River Transportation	Gillette, WY	$26,700		$26,700	D2007-OTRB-072
Ramblin Express, Inc.	Colorado Springs, CO		$183,000	$183,000	D2007-OTRB-073
Region IX					
Amador Stage Lines	Sacramento, CA		$70,275	$70,275	D2007-OTRB-074
Marin Airporter	San Rafael, CA	$122,000		$122,000	D2007-OTRB-075
Preferred Charters, LLC	Santa Rosa, CA		$392,300	$392,300	D2007-OTRB-076
Silverado Stages, Inc.	San Luis Obispo, CA	$279,360		$279,360	D2007-OTRB-077
Region X					
Northwestern Stage Lines	Spokane, WA	$63,022		$63,022	D2007-OTRB-078
Premier Alaska Tours, Inc.	Anchorage, AK		$44,970	$44,970	D2007-OTRB-079
TOTAL		**$11,925,000**	**$3,975,000**	**$ 15,900,000**	

[FR Doc. E8–19358 Filed 8–21–08; 8:45 am]
BILLING CODE 4910–57–C

Federal Register

Friday,
August 22, 2008

Part II

Department of Health and Human Services

45 CFR Part 162

Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 162

[CMS–0009–P]

RIN 0938–AM50

Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards

AGENCY: Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: This rule proposes to adopt updated versions of the standards for electronic transactions originally adopted in the regulations entitled, ''Health Insurance Reform: Standards for Electronic Transactions,'' published in the **Federal Register** on August 17, 2000, which implemented some of the requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These standards were modified in our rule entitled, ''Health Insurance Reform: Modifications to Electronic Data Transaction Standards and Code Sets,'' published in the **Federal Register** on February 20, 2003. This rule also proposes the adoption of a transaction standard for Medicaid Pharmacy Subrogation. In addition, this rule proposes to adopt two standards for billing retail pharmacy supplies and professional services, and to clarify who the ''senders'' and ''receivers'' are in the descriptions of certain transactions.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 21, 2008.

ADDRESSES: In commenting, please refer to file code CMS–0009–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the file code to find the document accepting comments.

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

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0009–P, P.O. Box 8014, Baltimore, MD 21244–1850.

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

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

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0009–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

FOR FURTHER INFORMATION CONTACT:

Lorraine Doo (410) 786–6597.

Gladys Wheeler (410) 786–0273.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period will be available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951. *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you may view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The web site address is: *http://www.gpoaccess.gov/fr/index.html.*

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I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Public Law 104–191, mandated the adoption of standards for electronically conducting certain health care administrative transactions between certain entities. In the August 17, 2000 final rule, the Secretary adopted standards for eight electronic health care transactions (65 FR 50312). The Secretary adopted modifications to some of those standards in a February 20, 2003 final rule (68 FR 8381). Since the standards compliance date of October 2003, a number of technical issues with the standards, including issues resulting from new business needs have been identified. Industry stakeholders submitted hundreds of change requests to the standards maintenance organizations, with recommendations for improvements to the standards. These requests were considered, and many were accepted, resulting in the development and approval of newer versions of the standards for electronic transactions. However, covered entities are not permitted to use the newer versions we are proposing herein until the Secretary of Health and Human Services (HHS) adopts them by regulation for covered transactions.

In addition to technical issues and business developments necessitating consideration of the new versions of the standards, there remain a number of unresolved issues that had been identified by the industry early in the implementation period for the first set of standards, and those issues were never addressed through regulation (for example, which is the correct standard to use for billing retail pharmacy supplies and professional services). This proposed rule addresses those outstanding issues.

A. Legislative Background

The Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in HIPAA, which was enacted on August 21, 1996. HIPAA requires the adoption and use of standards to facilitate the electronic transmission of certain health information and the conduct of certain business transactions.

Through subtitle F of title II of HIPAA, the Congress added to title XI of the Social Security Act (the Act) a new Part C, entitled ''Administrative Simplification.'' Part C of title XI of the Act consists of sections 1171 through 1179. These sections define various terms and impose several requirements on HHS, health plans, health care clearinghouses, and certain health care providers concerning the electronic transmission of health information.

Section 1171 of the Act establishes definitions for purposes of Part C of title XI for the following terms: code set, health care clearinghouse, health care provider, health information, health plan, individually identifiable health information, standard, and standard setting organization (SSO). Section 1172(a) of the Act makes any standard adopted under Part C applicable to: (1) Health plans; (2) health care clearinghouses; and (3) health care providers who transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard(s). Current standards are at 45 CFR part 162 subparts K through R.

Section 1172 of the Act requires any standard adopted by the Secretary under Part C of Title XI to be developed, adopted, or modified by a standard setting organization, except in the special cases where no standard for the transaction exists, as identified under section 1172(c)(2) of the Act. Section 1172 of the Act also sets forth consultation requirements that must be met before the Secretary may adopt standards. In the case of a standard that has been developed, adopted, or modified by an SSO, the SSO must consult with the following organizations in the course of the development, adoption, or modification of the standard: the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI) and the American Dental Association (ADA). Under section 1172(f) of the Act, the Secretary must also rely on the recommendations of the National Committee on Vital and Health Statistics (NCVHS) and shall also consult with appropriate Federal and State agencies and private organizations.

Section 1173(a) of the Act requires the Secretary to adopt transaction standards and data elements for such transactions, to enable the electronic exchange of health information for specific financial and administrative health care transactions and other financial and administrative transactions as determined appropriate by the Secretary. Under sections 1173(b) through (f) of the Act, the Secretary is also required to adopt standards for: specified unique health identifiers, code sets, security for health information, electronic signatures, and the transfer of certain information among health plans.

Section 1174 of the Act requires the Secretary to review the adopted standards and adopt modifications to the standards, including additions to the standards, as appropriate, but not more frequently than once every 12 months. Modifications must be completed in a manner that minimizes disruption and cost of compliance. The same section requires the Secretary to ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets. Moreover, if a code set is modified, the code set that is modified must include instructions on how data elements that were encoded before the modification may be converted or translated to preserve the information value of the data elements that existed before the modification.

Section 1175(b) of the Act provides for a compliance date not later than 24 months after the date on which an initial standard or implementation specification is adopted for all covered entities except small health plans, which must comply not later than 36 months after such adoption. If the Secretary adopts a modification to a HIPAA standard or implementation specification, the compliance date for the modification may not be earlier than the 180th day following the date of the adoption of the modification. The Secretary must consider the time needed to comply due to the nature and extent of the modification when determining compliance dates, and may extend the time for compliance for small health plans, if the Secretary deems it appropriate.

B. Regulatory History

On August 17, 2000, we published a final rule entitled, ''Health Insurance Reform: Standards for Electronic Transactions'' in the **Federal Register** (65 FR 50312) (hereinafter referred to as the Transactions and Code Sets rule). That rule implemented some of the HIPAA Administrative Simplification requirements by adopting standards for eight electronic transactions and for code sets to be used in those transactions. Those transactions were: health care claims or equivalent encounter information; health care payment and remittance advice; coordination of benefits; eligibility for a health plan; health care claim status; enrollment and disenrollment in a health plan; referral certification and authorization; and health plan premium payments. We defined these transactions and specified the adopted standards at 45 CFR part 162, subparts I and K through R.

The standards that we adopted were developed by two American National Standards Institute (ANSI) accredited standard setting organizations (commonly and hereinafter referred to as Standards Developing Organizations (SDO)): the National Council for Prescription Drug Programs (NCPDP)

and the Accredited Standards Committee ASC X12, which will hereinafter be abbreviated and referred to as X12. In our regulations and guidance materials to date, we have always referred to ''X12N'' where the ''N'' indicates the particular subcommittee. However, we have been informed by the X12 committee that it no longer uses the ''N'' to indicate the subcommittee. Therefore, in keeping with the current practice of the X12, we will not continue to use the ''N'' either, and we will simply refer to the standards of that organization as ''X12'' standards. We adopted the NCPDP Telecommunication Standard version 5.1 (hereinafter referred to as NCPDP 5.1) and its equivalent batch standard for retail pharmacy drug claims under the health care claims or equivalent encounter transaction, as well as the eligibility for a health plan transaction for retail pharmacy drugs, the retail pharmacy drug claims remittance advice transaction, and the coordination of benefits information transaction for retail pharmacy drug claims. We adopted a number of X12 standards, all in Version 4010, for the remaining transactions (see § 162.1101 through 1802).

On February 20, 2003, we published a final rule entitled, ''Health Insurance Reform: Modifications to Electronic Data Transaction Standards and Code Sets,'' in the **Federal Register** (68 FR 8381) (hereinafter referred to as the Modifications rule). In that rule, we adopted certain modifications to some of the standards for the eight electronic standard transactions. These modifications resulted in part from recommendations of the industry because the original versions of the X12 standards had certain requirements (for example, requiring information that is not available or not needed) that impeded implementation. Since the industry did not have extensive prior experience with the X12 standards, implementation problems were compounded. It is likely that this lack of expertise also contributed to limited input during the Version 4010 ballot process (to approve the ''original'' standards). For information about the ballot process for any particular SDO, interested parties should visit the individual Web sites for a full explanation of the process and how to participate. The result is that the standards were not thoroughly analyzed to identify problems before Version 4010 was adopted. The X12 agreed to create ''addenda'' to the original versions of the standards, called Version 4010A, in order to facilitate implementation for the industry, and the Secretary adopted those addenda into regulations in every instance where the Secretary had adopted Version 4010. (See 68 FR 8381). (Readers will note that we have removed the numeral ''1'' from the end of Version 4010/4010A1 for ease of reference. Since there is only one addendum, we did not feel the need to include the number ''1'' after each citation in this proposed rule.)

In Table 1 below, we summarize the full set of transaction standards adopted in the Transactions and Code Sets rule and as modified in the Modifications rule. The table uses abbreviations of the standards and the names by which the transactions are commonly referred, as a point of reference for the readers. The official nomenclature and titles of each standard and transaction are provided later in the narrative of this preamble.

TABLE 1—ADOPTED STANDARDS FOR HIPAA TRANSACTIONS

Standard	Transaction
ASC X12 837 D	Health care claims—Dental.
ASC X12 837 P	Health care claims—Professional.
ASC X12 837 I	Health care claims—Institutional.
ASC X12 837	Health care claims—Coordination of Benefits.
ASC X12 270/271	Eligibility for a health plan (request and response).
ASC X12 276/277	Health care claim status (request and response).
ASC X12 834	Enrollment and disenrollment in a health plan.
ASC X12 835	Health care payment and remittance advice.
ASC X12 820	Health plan premium payment.
ASC X12 278	Referral certification and authorization (request and response).
NCPDP 5.1	Retail pharmacy drug claims (telecommunication and batch standards).

C. Standards Adoption and Modification

In addition to adopting the first set of transaction standards and code sets, the Transactions and Code Sets rule adopted procedures for the maintenance of existing standards and for adopting new standards and modifications to existing standards (see § 162.910).

1. Designated Standards Maintenance Organizations (DSMO)

Section 162.910 sets out the standards maintenance process and defines the role of SDOs and the DSMO. An SDO is an organization accredited by the ANSI that develops and maintains standards for information transactions or data elements. SDOs include the X12, the NCPDP, and Health Level Seven (HL7). In August 2000, the Secretary designated six organizations (see Health Insurance Reform: Announcement of Designated Standard Maintenance Organizations Notice (65 FR 50373)) to maintain the health care transaction standards adopted by the Secretary, and to process requests for modifying an adopted standard or for adopting a new standard. The six organizations include the three SDOs referenced above. The other three organizations are the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), and the Dental Content Committee (DCC) of the American Dental Association. The DSMO operate through a coordinating committee. For additional information about the DSMO process and procedures, refer to the Web site at *http://www.hipaa-dsmo.org/Main.asp.*

2. Process for Adopting Modifications to Standards

In general, HIPAA requires the Secretary to adopt standards that have been developed by an SDO with certain exceptions. In addition to directing the Secretary to adopt standards, HIPAA, at section 1172(d) of the Act, also requires the Secretary to establish specifications for implementing each adopted standard.

The process for adopting a new standard or modifications to existing standards is described in the Transactions and Code Sets rule (65 FR 50312 at 50344) and implemented at § 162.910. Under § 162.910, the Secretary considers recommendations for proposed modifications to existing standards or a proposed new standard, only if the recommendations are

developed through a process that provides for—

- Open public access;
- Coordination with other SDOs;
- An appeals process for the requestor of the proposal or the DSMO that participated in the review and analysis if either of the preceding were dissatisfied with the decision on the request;
- An expedited process to address HIPAA content needs identified within the industry; and
- Submission of the recommendation to the NCVHS.

Any entity may submit change requests with a documented business case to support the recommendation to the DSMO. The role of the DSMO committee is to receive and manage those change requests. The DSMO review the request and notify the SDO of the recommendation for approval or rejection. If the changes are recommended for approval, the DSMO also notifies the NCVHS and suggest that a recommendation for adoption be made to the Secretary of HHS. Instructions for the DSMO process and access to the submission tools are available at *http://www.hipaa-dsmo.org.*

All of the modifications and the new transaction standard proposed in this rule were developed through a process that conforms with § 162.910. The suggested modifications and new standard recommended for approval by the DSMO were submitted to NCVHS for consideration. In 2007, the NCVHS conducted two days of hearings with health care providers, health plans, clearinghouses, vendors, and interested stakeholders on the adoption of the new ASC X12 Version 005010 Technical Reports Type 3 and the NCPDP Telecommunication Standard, Version D.0, to replace Versions 4010/4010A and the NCPDP Version 5.1. Testimony was also presented for the NCPDP Medicaid pharmacy subrogation standard (Version 3.0). A list of organizations that provided testimony to the NCVHS is available on the agenda for the July 2007 meetings, at *http://www.ncvhs.hhs.gov/070730ag.htm.* In addition to the standards organizations, other testifiers included Delaware Medicaid, MEDCO, Healthcare Billing and Management Association (HBMA), BlueCross BlueShield Association (BCBSA), Integra Professional Services, EDS, LabCorps, the American Dental Association, the American Hospital Association, the National Community Pharmacists Association (NCPA), the Medical Group Management Association (MGMA), the National Association of Chain Drug Stores (NACDS), the Workgroup for Electronic Data Interchange (WEDI) and Smith Premier. In a letter dated September 26, 2007 (available at *http://www.ncvhs.hhs.gov/070926lt.pdf*), the NCVHS submitted to the Secretary its recommendations to adopt the updated versions of standards as well as the NCPDP Medicaid pharmacy subrogation standard.

As noted above, and as indicated in the letter from NCVHS, HHS consulted with other Federal and State agencies and private organizations to gain input for this proposed rule regarding the adoption and implementation of standards. We also worked with WEDI specifically to conduct industry-focused information forums on implementation of the modified standards proposed in this rule.

3. Implementation Specifications and Technical Reports Type 3

Each adopted standard has operating rules that are documented in an implementation specification or guide. These implementation specifications or guides comprise ''the specific instructions for implementing a standard'' (§ 162.103). In addition to ensuring that specific data are communicated in the same way among trading partners, and providing instructions to users for implementing standards, these implementation specifications dictate field size limits and provide guidance for the type of information to be included in a particular field. The specificity that results enables health information to be exchanged electronically between any two entities, using the same instructions for format and content without losing the integrity of the data.

In 2003, the X12 initiated the concept of the Technical Reports Type 3 to promote consistency and coherency among information processing systems which use X12 standards and encourage uniform standards implementation. X12 Technical Reports are in three formats: Type 1 reports are tutorials that describe the intent of the authoring subcommittee and provide guidance on usage of the standard; Type 2 reports provide models of business practices and data flows to assist users in the development of software systems that would use the EDI transmissions; and Type 3 reports are implementation guides that address a specific business purpose (for example, a claim), and provide comprehensive instructions for the use and content of a transaction. The Technical Reports Type 3 are the updated equivalents of the X12 Implementation Guides referenced in the current HIPAA regulations. We note that no format or function differences exist between previous implementation specifications and Technical Reports Type 3. We reference Technical Reports Type 3 in the proposed regulation text in accordance with the way in which the X12 now refers to its implementation guides. Documents called Type 1 Errata are used to supplement published Technical Reports Type 3 that solve significant problems that prevent achievement of the business purpose.

NCPDP terminology has not changed since the adoption of the current HIPAA regulations. Therefore, the NCPDP standards continue to be referred to as implementation guides or specifications.

II. Provisions of the Proposed Rule

A. Proposed Adoption of X12 Version 005010 Technical Reports Type 3 for HIPAA Transactions

We propose to revise § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 to adopt the ASC X12 Technical Reports Type 3, Version 005010, hereinafter referred to as Version 5010, as a modification of the current X12 Version 4010 and 4010A1 standards, hereinafter referred to as Version 4010/4010A, for the HIPAA transactions listed below. In some cases, the Technical Reports Type 3 have been modified by Type 1 Errata, and these Errata are also included in our proposal. Covered entities conducting the following HIPAA standards would be required to use Version 5010:

- Health care claims or equivalent encounter information (§ 162.1101)
  - — Professional health care claims
  - — Institutional health care claims
  - — Dental health care claims
- Dental, professional, and institutional health care eligibility benefit inquiry and response (§ 162.1201)
- Dental, professional, and institutional referral certification and authorization (§ 162.1301)
- Health care claim status request and response (§ 162.1401)
- Enrollment and disenrollment in a health plan (§ 162.1501)
- Health care payment and remittance advice (§ 162.1601)
- Health plan premium payments (§ 162.1701)
- Coordination of Benefits (§ 162.1801)
  - — Dental health care claims
  - — Professional health care claims
  - — Institutional health care claims

Following is a brief description of the enhancements in the updated version of the standards and our rationale in support of its adoption.

Justification for Adopting Version 5010 TR3 Reports

Despite the changes made to Version 4010 that prompted the establishment of Version 4010A, which was adopted in the Modifications rule, operational and technical gaps still exist in Version 4010A. In addition, it has been more than 5 years since implementation of the original standards, and business needs have evolved during this time. While the implementation specifications continue to improve with each new version, deficiencies in the adopted versions continue to cause industry-wide issues. These deficiencies in the current implementation specifications have caused much of the industry to rely on ''companion guides'' created by health plans to address areas of Version 4010/4010A that are not specific enough or require work-around solutions to address business needs. These companion guides are unique, plan-specific implementation instructions for the situational use of certain fields and/or data elements that are needed to support current business operations. We believe that industry reliance on companion guides has minimized some of the potential benefits offered by the standards because each guide has a different set of requirements, making full standardization nearly impossible. Furthermore, as the industry worked with the standards and became more adept at using them, opportunities for improvement became apparent and were included in subsequent versions of the implementation specifications. It also became apparent that dependence on companion guides could be greatly reduced, if not eliminated, if proposed modifications were ultimately adopted for use by the industry.

As stated earlier, in the years following the compliance deadline, hundreds of requests to upgrade the standards have been submitted by the industry to the DSMO Steering committee. These requests have been made in accordance with the DSMO Change Request process, described in the Transactions and Code Sets rule. The DSMO Steering committee has evaluated approximately five hundred requests for changes to Version 4010/4010A. Version 5010 changes significantly improve the functionality of the transactions and correct problems encountered with Version 4010/4010A. Change Description Guides detailing the specific changes made to each new version are available at *http://www.wpc-edi.com.* The Medicare Fee-for-Service program is evaluating the impact of implementing Version 5010 in the future, and has completed a gap analysis of the standards. Medicare has prepared a comparison of the current X12 HIPAA EDI standards (Version 4010/4010A) with Version 5010 and the NCPDP EDI standards Version 5.1 to D.0, and has made these side-by-side comparisons available to other covered entities and their business associates on the CMS Web site: *http://www.cms.hhs.gov/ElectronicBillingEDITrans/18_5010D0.asp*.

The areas of improvement included in Version 5010 can be grouped into four main themes. Each theme is discussed in detail below:

Front Matter/Education—Information in the front matter (hereinafter referred to as the Front Matter section) of Version 5010 now provides clearer instructions. Ambiguous language has been eliminated and the rules for required and situational data elements are more clearly defined.

Technical Improvements—Technical improvements in Version 5010 include new guidelines that use the same data representation for the same purposes across all of the transactions for which Version 5010 is used. This reduces ambiguities and reduces the number of times that the same data could have multiple codes or qualifiers, or from appearing in different segments for the same purpose. Consistent data representation reduces ambiguities that result from the same data having multiple codes or qualifiers and from the same data appearing in different segments in different transactions. In other words, ambiguous language has been eliminated, the rules for required and situational data elements are more clearly defined, and instructions for many business processes have been clarified.

Structural Changes—Modifications to the physical components of the transaction have been made. New segments and new data elements have been added and data elements have been modified or removed to make the data elements longer, shorter, or of a different data type to add functionality and improve consistency. In some cases, new ''composites,'' defined as a collection of related data elements, have been added in order to ensure that related data is reported and received in the same section of the transaction instead of spread out in different areas. This increases the accuracy of processing because programming can be consistent for each transaction.

Data Content—Redundant and unnecessary data content requirements have been removed to eliminate confusion for implementers. Additional requirements have been added where needed to clarify existing data content requirements.

The following section includes a brief summary of changes for each of the versions of the implementation guides. We note that some of the implementation guides had significant modifications while others were changed only moderately. In the following discussions for each transaction, we use short-hand for referring to the current and modified versions of the standard. Instead of writing out the full name of the standard in each case, we refer to ''Version 4010/4010A'' and ''Version 5010.'' The Version 4010/4010A and Version 5010 short-hand refers to the particular transaction standard discussed in each section below. For example, in the first section below, we address the Health Care Claims or Equivalent Encounter Information transaction for institutional health care claims. Rather than refer to the ASC X12 837I, Version 4010/4010A and the X12 837 Version 5010 Technical Report Type 3 for the Health Care Claims or Equivalent Encounter Information transaction for institutional claims, we refer to Version 4010/4010A and Version 5010, respectively, with the understanding that we are referring to those versions in the context of the health care claims or equivalent encounter information transactions for institutional claims. This is true also for our discussion of the NCPDP transaction standards. Finally, the standards are presented in the order we believe best represents the level of utilization within the industry; in other words, the transactions which are used most often by the industry, such as claims and eligibility verification, are listed before lesser used transactions, such as enrollment and premium billing. In the section below, the order of the transactions does not follow the order of the regulation text. However, in the regulation text section of this proposed rule, the standards are represented in the same order in which they have been published in each of the earlier regulations.

Health Care Claims or Equivalent Encounter Information Transaction (837)

Institutional Health Care Claims (837I)

We propose to revise § 162.1102 by adding a new paragraph (c)(4) that would replace the ASC X12N 837I Version 4010/4010A with the Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and Type 1 Errata to Health Care Claim: Institutional for the Health Care Claims

or Equivalent Encounter Information Transaction for institutional claims.

Version 4010/4010A does not provide a means for identifying an ICD–10 procedure or diagnosis code on an institutional claim. Version 5010 anticipates the eventual use of ICD–10 procedure and diagnosis codes and adds a qualifier as well as the space needed to report the number of characters that would permit reporting of ICD–10 procedure and diagnosis codes on institutional health care claims.

Other significant changes include the following:

• Version 5010 separates diagnosis code reporting by principal diagnosis, admitting diagnosis, external cause of injury and reason for visit, allowing the capture of detailed information (for example, mortality rates for certain illnesses, the success of specific treatment options, length of hospital stay for certain conditions, and reasons for hospital admissions).

• Version 4010/4010A does not allow for the identification of a ''Present on Admission'' indicator (POA) on the institutional claim. Present on Admission means the condition or diagnosis that is present at the time the order for inpatient admission occurs—conditions that develop during an outpatient encounter, including emergency department, observation, or outpatient surgery, are considered as present on admission. This information is being captured through a workaround in Version 4010/4010A by placing this information in an unassigned segment. This has created confusion for hospitals and has limited access to information that is critical to identifying hospital acquired conditions and the ability to track utilization of the POA indicator and treatment outcomes as specified by section 5001 of the Deficit Reduction Act. Version 5010 allows the POA indicator to be associated with each individual diagnosis code allowing the capture of detailed information (for example, mortality rates for certain illnesses, length of hospital stay for certain conditions and reasons for hospital admissions).

• Version 5010 includes clear and precise rules that clarify how and when the NPI is to be reported. Instructions require submitters to report the same organizational type NPI in the same position for all payers. This improves the accuracy of information that is needed to conduct coordination of benefits by ensuring that the NPI information that is submitted to a secondary or tertiary payer reflects the NPI information that was processed by the primary payer. Version 4010/4010A does not have clear rules about how an NPI should be reported for subparts, or how to identify atypical providers (for example, taxi services, home and vehicle modifications services, and respite services that are not required to obtain an NPI), resulting in confusion among providers about who needs an NPI and when an NPI for a subpart or an individual provider should be reported.

• Version 5010 provides clear definitions and precise rules with instructions for consistently reporting provider information in the same position and with the same meaning throughout the transaction. Version 4010/4010A lacks a clear definition for the various types of providers (other than attending and operating) who participate in providing health care and who could be named in the claim transaction (for example, ordering provider and referring provider).

Version 5010 makes programming more efficient because it uses the same structure for all data elements across the transactions for which 5010 is used. Therefore, the structure for patient information in the institutional health care claims transaction would be the same as that for eligibility for a health plan transaction. Version 4010/4010A does not structure certain data (for example, patient information) consistently with the standards for other transactions, such as the eligibility for a health plan transaction.

• Professional health care claims (837P).

We propose to revise § 162.1102 by adding a new paragraph (c)(3) that would replace the ASC X12N 837P Version 4010/4010A with the 837 Health Care Claim: Professional ASC X12 Technical Report Type 3 for the Health Care Claims or Equivalent Encounter Information Transaction for professional claims.

Like the institutional health care claim transaction, Version 4010/4010A does not provide a means for identifying an ICD–10 diagnosis code on a professional claim. Version 5010 anticipates the eventual use of ICD–10 diagnosis codes and adds a qualifier as well as the space needed to report the number of characters that would permit reporting of ICD–10 diagnosis codes on professional claims.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• Version 5010 only allows the reporting of minutes for anesthesia time, ensuring consistency and clarity across transactions. Version 4010/4010A lacks consistency in allowing for the reporting of anesthesia time, in either units or minutes. This inconsistency creates confusion among providers and plans, and frequently requires electronic or manual conversions of units to minutes or vice versa, depending on a health plan's requirement, and is especially complicated when conducting COB transactions with varying requirements among secondary or tertiary payers.

• Version 5010 allows ambulance providers to report pick-up information for ambulance transport electronically and makes it a requirement on all ambulance claims. Version 4010/4010A does not allow ambulance providers to report pick-up information for ambulance transport. Plans that need this information to adjudicate an ambulance claim must request this information after the claim is received. This means that providers are required to submit the information separately or on paper, which complicates the claim submission substantially. Version 5010 includes an implementation note that states that the provider specialty information applies to the entire claim unless there are individual services where the provider specialty information differs. This feature eliminates redundant reporting. Version 4010/4010A contains redundant requirements for reporting a referring provider's medical specialty when a claim contains more than one service, and the referring provider specialty information differs for at least one of the services.

• Dental health care claims (837D).

We propose to revise § 162.1102 by adding a new paragraph (c)(2) that would replace the ASC X12N 837D Version 4010/4010A with the 837 Health Care Claim: Dental ASC X12 Technical Report Type 3 and Type 1 Errata for Health Care Claims or Equivalent Encounter Information for dental claims.

Certain services performed by dentists are considered to be medical services and are covered as medical benefits by insurance plans. In Version 4010/4010A, a dental claim cannot be processed as a medical claim because not all the required or situational information for a medical claim is included in the dental claim. In Version 5010 for dental claims, data requirements are closely aligned with the data requirements for medical claims, which supports coordinating benefits between dental and medical health plans.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• Version 5010 includes a designated location for treatment start and stop

dates for dental crowns or bridges, which health plans need to appropriately administer their dental benefits. Version 4010/4010A does not allow for this information to be reported.

• Version 5010 supports the reporting of specific tooth numbers with the International Tooth Numbering System (ITNS) code. Version 4010/4010A does not support this reporting, which makes submitting claims for dental services that may be covered under a medical plan complicated and burdensome. The services typically relate to wisdom teeth extraction and traumatic dental injuries, and are generally provided by oral and maxillofacial surgeons. Since these services often are covered by a medical benefit, they are reported on the 837 professional claim. Without support for the ITNS on the 837 professional claim, providers face denials, claim re-works and the manual submission of paper documentation to provide the tooth number information that is needed by plans to properly adjudicate claims and electronically conduct coordination of benefits. Version 5010 eliminates these cumbersome processes by providing a standardized field for reporting the ITNS code on claims that may be required to report certain dental services on an 837 professional claim, rather than the dental version.

• Version 5010 includes an enhancement that supports the reporting of an address for the place of treatment for dental claims. Version 4010/4010A does not support the recording of this information. The place of treatment is typically the dentist's address and it is needed by health plans for claims adjudication. The support for this information is available in Version 4010/4010A but only for institutional and professional claims.

• Version 5010 requires a first name only when the entity is a person, whereas Version 4010/4010A requires a first name even in instances when the entity is not a person. The deficiency in Version 4010/4010A means that, even if an organization or company is the subscriber for a workers' compensation claim, in which case there would be no first name, the submitter is still required to provide a first name.

Health Care Payment and Remittance Advice Transaction (835)—For All Claim Types

We propose to revise § 162.1602 by adding a new paragraph (c) that would replace the ASC X12N 835 Version 4010/4010A with the 835 Health Care Claim Payment/Advice ASC X12 Technical Report Type 3 for the Health Care Payment and Remittance Advice transaction. This would apply to all claim types, including retail pharmacy claims.

Many of the enhancements in Version 5010 involve the Front Matter section of the Technical Report Type 3, which contains expanded instructions for accurately processing a compliant 835 transaction. Version 5010 provides refined terminology for using a standard, and enhances the data content to promote clarity. The benefits of these refinements could include more accurate use of the standard, reduction of manual intervention and could motivate vendors and billing services to provide a more cost-effective solution for the submission and receipt of electronic remittance advice transactions.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• Version 5010 makes improvements to permit better use of remittance advice by tightening business rules and reducing the number of available code value options. Version 4010/4010A for remittance advice lacks standard definitions and procedures for translating remittance information and payments from various health plans to a provider which makes automatic remittance posting difficult.

• Version 5010 provides instructions for certain business situations where none had existed before. For example, Version 5010 instructs providers on how to negate a payment that may be incorrect and post a correction.

• Version 5010 for the 835 transaction does not affect the processing of Version 4010/4010A claim transactions. This compatibility with the earlier standard would permit implementers to begin testing Version 5010 for the 835 transaction before the compliance date, and, at the same time, continue to process 837 claims using Version 4010/4010A. This flexibility is important because there may be a transition period with claims for services rendered before the compliance date that will be in the older version of the standard because data elements required in Version 5010 might not have been captured at the time services were rendered.

• Version 5010 includes a new Medical Policy segment that provides more up-to-date information on payer policies and helps in detail management, appeals, and reduces telephone and written inquiries to payers. The new segment helps providers locate related published medical policies that are used to determine benefits by virtue of the addition of a segment for a payer's URL for easy access to a plan's medical policies. Version 4010/4010A does not provide the ability to include information or resources for policy-related payment reductions or omissions.

• Version 5010 eliminates codes marked ''Not Advised,'' but leaves the code representing ''debit'' as situational, with instructions on how and when to use the code. Version 4010/4010A contains codes marked ''Not Advised,'' which means that the guide recommends against using it, but does not prohibit its use. For example, in Version 4010/4010A, there are codes to indicate whether a payment is a debit or a credit, and the debit code is marked ''Not Advised'' because the transaction is a payment, and a credit code is expected instead. There is no use for the debit code, so the instruction ''Not Advised'' appears for that field.

• Version 5010 provides clear instructions for use of the claim status indicator codes. Version 4010/4010A includes status codes that indicate a primary, secondary, or tertiary claim, but no instructions for the use of these codes. This creates confusion when a claim is partially processed, or when a claim is processed but there is no payment.

Enrollment and Disenrollment in a Health Plan (834)

We propose to revise § 162.1502 by adding a new paragraph (c) that would replace the ASC X12N 834 Version 4010/4010A with the 834 Benefit Enrollment and Maintenance ASC X12 Technical Report Type 3 for the Enrollment and Disenrollment in a health plan transaction.

The most significant differences between Version 4010/4010A and Version 5010 for the enrollment and disenrollment in a health plan transaction is the addition of functionality in Version 5010 that did not exist in Version 4010/4010A. For example, Version 5010 can use ICD–10 diagnosis codes for reporting pre-existing conditions and additional ICD–10 disease classifications. This functionality was added in anticipation of the adoption of the ICD–10 code sets.

Other changes in Version 5010 that were added in response to requests for improvements to Version 4010/4010A include:

• Version 5010 adds the ability to designate certain information as confidential and restrict access to member information. This new function provides privacy protection by safeguarding confidential information.

• Version 5010 adds maintenance reason codes to explain coverage

changes. The new codes reflect changes in student status, age limitations, additional coverage information, life partner changes, termination due to non-payment, and other changes. This information is important for establishing coverage patterns and recording accurate information on coverage status.

- Version 5010 provides the ability to report enrollment subtotals by employees and dependents or grand totals, unlike Version 4010/4010A; although not a critical change, this is a feature of Version 5010 that facilitates use of the 834 transaction.
- Version 5010 eliminates date range confusion by adding fields for a ''start'' date and an ''end'' date. Version 4010/4010A lacks definitions and instructions for reporting date ranges that indicate coverage ''to'' a certain date, versus coverage ''through'' a certain date, and instructions as to when to send the dates of effectiveness for coverage changes. Without accurate coverage effectiveness and coverage change information, the administration of enrollment and disenrollment in a health plan becomes inefficient and cumbersome and frequently requires manual intervention, negating the benefits of electronic data interchange (EDI).

Health Plan Premium Payments (820).

We propose to revise § 162.1702 by adding a new paragraph (c) that would replace the ASC X12N 820 Version 4010/4010A with the 820 Payroll Deducted and Other Group Premium Payment for Insurance Products, ASC X12 Technical Report Type 3 for the Health Plan Premium Payments Transaction.

A deficiency in Version 4010/4010A is the inability for health plan sponsors to report additional deductions from payments. The addition of this data element is an important improvement in Version 5010 because it helps reduce confusion for health plans when payments are not the amount expected. Version 4010/4010A does not have a way to indicate the method used to deliver the remittance. Version 5010 includes an indicator for the delivery method, and options include file transfer, mail, and online. This permits trading partners to select and indicate the method that best meets their business needs.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

- Version 5010 permits a health plan sponsor to adjust an entire transaction for a previous payment without tying it to an individual member record. Version 4010/4010A requires a health plan sponsor to link a transaction payment adjustment for a previous payment to an individual member record, creating extra work and additional administrative tasks.
- To eliminate confusion, Version 5010 changes the premium remittance detail information from ''situational'' to ''required,'' so that all entities must provide the specific data regarding premiums. In Version 4010/4010A, premium remittance detail information is situational and only required for HIPAA transactions. Plan sponsors always use the transaction for premium payments to health plans so the transaction is always a HIPAA transaction and, therefore, premium remittance detail information is always required.

Eligibility for a Health Plan (270/271).

We propose to revise § 162.1202 by adding a new paragraph (c)(2) that would replace the ASC X12N 270/271 Version 4010/4010A with the 270/271 Health Care Eligibility/Benefit Inquiry and Information Response ASC X12 Technical Report Type 3 for the Eligibility for a Health Plan Transaction. This transaction is used to determine eligibility for institutional, professional and dental services, and for eligibility and benefit inquiries between prescribers and Part D Plan Sponsors. (It is not used between pharmacies and health plans for a pharmacy's eligibility inquiries—that standard is an NCPDP standard, and its use is discussed in the section on Version D.0 later in this preamble.)

Version 4010/4010A does not require health plans to report relevant coverage information, for example, coverage effectiveness dates—health plans are only required to provide a response that coverage does exist. Version 5010 corrects this deficiency by requiring the payer to report specific coverage information (for example, the name of plan coverage, beginning effective date, benefit effective dates, and primary care provider (if available)). This additional information significantly improves the value of the transaction to the provider community.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

- Version 5010 adds nine categories of benefits that must be reported if they are available to the patient. Some examples of those categories are pharmacy, vision, and mental health. Version 4010/4010A contains no requirement to report categories of benefits.
- Version 5010 adds 38 additional patient service type codes to the ones that are available in Version 4010/4010A. This expands the use of patient service type codes available to submit in an eligibility inquiry. The use of a more specific patient services type code enriches the data that is returned in the eligibility response, matching the information in the eligibility response to that in the eligibility inquiry.
- Version 5010 provides clearer instructions for describing subscriber and dependent relationships. Health plan subscriber and dependent relationships are unclear in Version 4010/4010A, creating ambiguity and confusion about when to use ''subscriber'' and when to use ''dependent'' when one of them is also the patient.

Referral Certification and Authorization (278).

We propose to revise § 162.1302 by adding a new paragraph (c)(2) that would replace the ASC X12N 278 Version 4010/4010A with the 278 Health Care Services Request for Review and Response ASC X12 Technical Report Type 3 and Type 1 Errata for the Referral Certification and Authorization transaction.

This transaction is not commonly used in the industry today because of the many implementation constraints of Version 4010/4010A. These constraints include the inability to report specific information on patient conditions (for example, mental status), functional limitations of the patient (for example, handicapped), and the specialty certifications of a provider. Version 4010/4010A also does not provide a way for the requestor to limit the number of occurrences of a service within a defined time frame (for example, limiting the number of visits to three within a ninety-day period). Version 5010 corrects these deficiencies.

Version 5010 includes the following additional improvements over Version 4010/4010A:

- Version 5010 includes rules and separate implementation segments for key patient conditions, including: ambulance certification information; chiropractic certification; durable medical equipment information; oxygen therapy certification information; patient functional limitation information; activities currently permitted for the patient information; and patient mental status information. Version 4010/4010A lacks differentiating rules for various conditions, making the standard cumbersome to use for both providers and health plans.

• Version 5010 supports or expands support for, a variety of business cases deemed important by the industry, including: Medical services reservations (permitting requesters to reserve a certain number of service visits within a defined period of time, for example, number of physical therapy visits); dental service detail (for tooth numbering and other dental related services); and ambulance transport requests to capture multiple address locations for multiple trips.

• Version 5010 supports or expands authorization exchanges, including requests for drug authorization procedure code modifiers and patient state of residence, which may be important from a coverage determination standpoint. Version 4010/4010A does not support authorizations for drugs and certain pharmaceuticals, and a number of other common authorization exchanges between covered entities.

Health Care Claim Status (276/277)

We propose to revise § 162.1402 by adding a new paragraph (c) that would replace the ASC X12N 276/277 Version 4010/4010A with the Health Care Claim Status Request and Response ASC X12 Technical Report Type 3 and Type 1 Errata for the Health Care Claim Status Transaction, for institutional, professional and dental claims.

One of the deficiencies of the Version 4010/4010A 276 inquiry is that it does not identify prescription numbers and the associated 277 response cannot identify which prescription numbers are paid or not paid at the claim level of the transaction. The ability to identify a prescription by the prescription number is important for pharmacy providers when identifying claims data in their systems. Version 5010 includes new functionality that allows for identification of prescription numbers and the associated response allows for identification of which prescription numbers are paid or not paid at the claim level.

Other changes in Version 5010 that were added in response to requests for improvements to Version 4010/4010A include:

• Version 5010 eliminates a number of requirements to report certain data elements which are considered sensitive personal information specific to a patient, and which are not necessary to process the transaction. The Version 4010/4010A requirements for the collection and reporting of sensitive patient health information have raised concerns about privacy and minimum necessary issues. For example, the Version 4010/4010A standard requires the subscriber's date of birth and insurance policy number, which often is a social security number. This information is not needed to identify the subscriber because the policy number recorded for the patient already uniquely identifies the subscriber.

• To reduce reliance on companion guides, and ensure consistency in the use of the Implementation Guides, situational rules that were ambiguous in Version 4010/4010A are clarified in Version 5010. For example, Version 4010/4010A contains a number of situational rules that are unclear and open to different interpretations. Based on industry requests for changes, the DSMO reviewed all of the 4010/4010A situational rules and revised each standard as appropriate to reduce multiple interpretations. For example, Version 5010 clarifies the relationships between dependents and subscribers, and makes a clear distinction between the term ''covered status'' (whether the particular service is covered under the benefit package) and ''covered beneficiary'' (the individual who is eligible for services). Since Version 4010/4010A does not provide clear rules for the interpretation of these terms, industry use of the fields is inconsistent, and subject to entity-specific determinations. An additional example of a clarification is the creation of a new section in the Version 5010 Referral Certification and Authorization transaction, where a separate segment was created to allow for the entry of information to clearly indicate that a patient's medical condition met certification requirements for ambulance or oxygen therapy. The creation of a specific section to capture such information eliminates the need to request or send that information later.

• Version 5010 implements consistent rules across all TR3s regarding the requirement to include both patient and subscriber information in the transaction. Some current implementation guides (Version 4010/4010A) require that subscriber information be sent even when the patient is a dependent of the subscriber and can be uniquely identified with an individual identification number, whereas other transactions (for example, eligibility for a health plan inquiry (270) and referral certification and authorization request (278)) permit sending only the patient dependent information if the patient has a unique member ID. These standards do not require the subscriber ID. The requirement to include the subscriber information with the dependent member information for a uniquely identifiable dependent is an administrative burden for the provider.

• Version 5010 provides clear instructions for users on how to use the transaction in either batch or real time mode. Version 4010/4010A does not provide any such guidance, which is needed by the industry.

Coordination of Benefits (COB)—(837)

We propose to revise § 162.1802 by adding new paragraphs (c)(2), (c)(3), and (c)(4) that would replace the ASC X12N 837 Version 4010/4010A implementation guides for the Coordination of Benefits (COB) Transaction, with Version 005010 Technical Report Type 3 and Type 1 Errata for institutional, professional and dental claims. COB is a claim function included in each of the individual named claim Type 3 Technical Reports (837I, 837P and 837D).

There are a number of deficiencies with Version 4010/4010A, including the lack of clear instructions for several important scenarios, including how to create a COB claim when the prior payer's remittance information came to the provider in a paper format and how a receiver can calculate a prior payer's allowed amount. Additional deficiencies that have made coordination of benefits transactions among payers difficult is the presence of statements such as ''if needed by a payer for adjudication'' and similar statements that have allowed for varying interpretations within the health care industry. These obstacles to successfully completing an electronic compliant COB transaction using Version 4010/4010A, and accepting and adjudicating COB transactions among a variety of payers, have been removed or significantly mitigated in Version 5010.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• A number of sections have been added or modified in Version 5010 to provide the broad-based instructions necessary to ensure a standard implementation of COB transactions, including instructions for balancing dollar amounts on a claim.

• The Front Matter section of Version 5010 includes an explanation of the destination payer's specific information (for example, claims data and provider identifiers that are needed for conducting COB).

B. Proposed Adoption of NCPDP Telecommunication Standard Implementation Guide Version D Release O (D.0) and Equivalent Batch Standard Batch Implementation Guide, Version 1, Release 2 (1.2) for Retail Pharmacy Transactions

We propose to revise § 162.1102, § 162.1202, § 162.1302, and § 162.1802 by adding new paragraphs (c)(1) to each of those sections to adopt the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2) (hereinafter collectively referred to as Version D.0) in place of the NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (hereinafter collectively referred to as Version 5.1), for the following retail pharmacy drug transactions: Health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits.

Since the adoption of Version 5.1 as a transaction standard in the Transactions and Code Sets rule, the industry has submitted requests to NCPDP for modifications to Version 5.1. These modification requests were for similar reasons as those for the X12 standards—changing business needs, many necessitated by the requirements of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).

In NCVHS hearings held in July 2007, industry stakeholders cited business needs that would be addressed by the increased functionality in Version D.0 to include:

- *Enhanced guidance for Coordination of Benefits (COB).* In Version D.0, extensive clarification is made to the implementation guide for coordination of benefits processing. New data elements, for example, patient responsibility and benefit stage were added, along with a refined use of the Other Coverage Code field.
- *Processing of Medicare Part D claims.* Changes in Version D.0 include the addition of three new data elements and rejection codes.
- *Enhanced eligibility checking.* Version D.0 provides more complete eligibility information for Medicare Part D and other insurances.
- *Specific COB for Medicare Part D.* Version D.0 includes identification of patient responsibility, benefit stage, and coverage gaps on secondary claims.
- *Streamlined claims processing for compounded drugs.* In Version D.0, the compound segment has been modified to allow for the billing of multiple ingredients. To standardize this process, the two alternative ways of billing compounded claims have been removed.

As a result of the hearings, the NCVHS Subcommittee on Standards and Security determined that the business needs identified by the industry would be met by Version D.0. The NCVHS expressed its support for Version D.0, and recommended that it be proposed for adoption as a HIPAA transaction standard through rulemaking. Based on the comments from industry stakeholders (as discussed above), the NCVHS specifically referenced several of the improvements in Version D.0, including: The modified field and segment defined situations; resolution of the situational versus optional data requirements to accommodate the HIPAA privacy regulations; and segment usage matrices that clarify which segments and fields are sent for each transaction type, and segments and fields within each transaction type. It also cited the enhancements made to accommodate Medicare Part D, which include the addition of a ''facilitator'' entity and eligibility transaction to provide coded patient eligibility information for Medicare Part D and enhancements to identify and process Medicare Part D long term care claims. Enhancements with respect to Medicare Part B claims include additional segments for processing Medicare certificates of medical necessity, new data elements for processing those transactions, and assistance in the crossover of claims from Medicare to Medicaid. Finally, the NCVHS stated that Version D.0 also supports the following: COB and collection of rebates for compounded claims; clarification for pricing guidelines; the addition of new data elements that give more specificity to the COB process; a new section on prior authorization added to the implementation guide; a prescription/service reference number increase to 12 digits; and transaction codes for service billings.

Because we believe Version D.0 would better support the business needs of the industry, for the reasons cited by the NCVHS, we propose to adopt Version D.0. We solicit comments regarding the proposed adoption of Version D.0 as the HIPAA standard, set forth in proposed revisions to § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

C. Proposed Adoption of a Standard for Medicaid Pharmacy Subrogation: NCPDP Medicaid Subrogation Implementation Guide, Version 3.0 for Pharmacy Claims

We propose to add a new subpart S to 45 CFR part 162 to adopt a standard for the subrogation of pharmacy claims paid by Medicaid. The transaction would be the Medicaid Pharmacy Subrogation transaction, defined at proposed § 162.1901, and the new standard would be the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007 (hereinafter referred to as Version 3.0) at proposed § 162.1902. The standard would be applicable to Medicaid agencies in their role as health plans, but not to providers or health care clearinghouses because this transaction is not utilized by them. As a condition of Medicaid eligibility, an individual must assign to the State Medicaid agency his or her rights to payments for medical services from other liable third parties. This allows the Medicaid agency the right to stand in the place of the Medicaid recipient for the purpose of collecting reimbursement from liable third parties wherever the Medicaid agency has paid claims on behalf of a Medicaid recipient. This is referred to as ''Medicaid subrogation.''

Federal law requires, with some exceptions, that Medicaid be the payer of last resort. Health plans that are legally required to pay for health care services received by Medicaid recipients are to pay for services primary to Medicaid. However, Medicaid agencies sometimes pay claims for which a third party may be legally responsible. This can occur when the Medicaid agency is not aware of the existence of other coverage. There are also specific circumstances for which States are required by Federal law to pay claims and then seek reimbursement afterward. Whenever Medicaid pays claims for which another party is legally responsible, the State is required to seek recovery.

For the purpose of adopting a HIPAA standard, we propose to define a Medicaid pharmacy subrogation transaction as the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the State has paid on behalf of a Medicaid recipient.

A majority of health plans use a pharmacy benefit manager (PBM) to manage prescription drug coverage and handle claims processing. Some health

plans administer the prescription coverage in-house, but contract with a claims processor to handle claims adjudication. A few of the large health plans perform their own claims processing. When PBMs process claims on behalf of health plans, they are considered to be business associates of the health plans. Section 162.923(c) requires a covered entity that chooses to use a business associate to conduct all or part of a transaction on behalf of the covered entity, to require the business associate to comply with all applicable requirements of the HIPAA regulations. Therefore, while entities such as PBMs and claims processors do not necessarily have ultimate financial liability, to the extent they are required by contract or otherwise to process claims on behalf of health plans, they will need to be able to receive the Medicaid pharmacy subrogation transaction in the standard format.

There are many different formats utilized for submitting Medicaid pharmacy subrogation claims. To meet the many different requirements of the third party payers, States must maintain and utilize a variety of pharmacy billing formats. This is because different third party payers require different pieces of information. According to a study conducted by the Office of the Inspector General (OIG) entitled, *''Medicaid Recovery of Pharmacy Payments from Liable Third Parties''* (OEI–3–00–00030, August 2001, available at *http://oig.hhs.gov/oei/reports/oei-03-00-00030.pdf*), 29 States indicated that the lack of universal formatting and data elements on pharmacy claims leads to the denial of Medicaid claims, contributing to millions of dollars of lost revenue to Medicaid. States have had to work through numerous changes and challenges to submit claims that are correctly formatted for various health plans. When States' claims are denied for formatting or missing data, and have to be reworked and resubmitted; there is additional administrative and financial burden on States and third parties. According to the OIG study, some PBMs have reimbursed claims at a lower rate as a penalty for the claim being in the wrong format. In order to recover Medicaid funds, some States have found it necessary to recoup from the pharmacies and it is left up to the pharmacies to seek reimbursement from the third party payers.

In 1999, representatives from CMS and the Medicaid agencies began working closely with NCPDP to develop a standard electronic format that could be used to facilitate electronic transmission of pharmacy subrogation claims from Medicaid agencies to other payers. The standard combines a subset of elements from the NCPDP Version 5.1 drug claim standard with additional elements that Medicaid specifically needs to conduct subrogation, such as the Medicaid paid amount and the Medicaid agency identification number. The additional Medicaid-specific elements had to be placed in other NCPDP fields that were not discretely defined in Version 5.1. In June 2000, as a result of these collaborative efforts, NCPDP issued the Medicaid Subrogation Implementation Guide Version 2.0 for the Batch Standard.

At least two-thirds of the States utilize Version 2.0 voluntarily, many through the use of a business associate that bills pharmacy claims on the State's behalf. The States, or their business associates, use the NCPDP format with some modifications to accommodate the various other health plan requirements. There are at least ten major third party payers that have entered into an agreement with States and/or their business associates to accept the NCPDP format. However, the absence of full standardization now presents challenges for States, which must continue to maintain and use many billing formats.

We did not adopt a standard for Medicaid pharmacy subrogation at the time the first set of HIPAA transaction standards were adopted because it was not one of the specified transactions mandated in the law. However, we believe that, in light of the challenges noted above, deriving from the lack of full standardization, it is now appropriate to propose a standard for the Medicaid pharmacy subrogation transaction. Section 1173(a)(1)(B) of the Act authorizes the Secretary to adopt standards for any other financial and administrative transactions as deemed appropriate, consistent with the goals of improving the operation of the health care system and reducing administrative costs. We believe that adopting a standard for Medicaid pharmacy subrogation would facilitate electronic data interchange; thereby reducing administrative costs and improving the operations of the health care system by eliminating multiple formats and methods of performing this transaction.

We solicit comments regarding the proposed adoption of the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0 as the HIPAA standard for the Medicaid pharmacy subrogation transaction, and the proposed dates for compliance with the standard addressed in proposed § 162.1902.

D. Proposed adoption of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard D.0 and the Health Care Claim: Professional ASC X12 Technical Report Type 3 for Billing Retail Pharmacy Supplies and Services

We propose to revise § 162.1102 to adopt both Version D.0 and the 837 Health Care Claim: Professional ASC X12 Technical Report Type 3 for billing retail pharmacy supplies and professional services. The use of either standard would be determined by trading partner agreements.

The Transactions and Code Sets rule adopted two transaction standards relating to the billing of retail pharmacy claims. Version 5.1 is required for the transmission of retail pharmacy drug claims, and the X12 837 for professional services and supplies. (§ 162.1102). The final rule, however, does not define what or who constitutes ''retail pharmacies'' and further, what a ''retail pharmacy drug claim'' is in the context of the NCPDP, Version 5.1 standard. The regulations also do not specify, define, or describe the items or services that are to be billed on the X12N 837P standard, only that the services are ''health care services.'' As a result, different interpretations of the regulations exist as to whether a ''retail pharmacy drug claim,'' which is to be billed using Version 5.1, includes claims only for drug products, for drug products and associated pharmacy services and supplies, or for drug products and any retail pharmacy services or supplies. CMS has interpreted the regulation as requiring that Version 5.1 be used only for drug products and that the X12N 837P be used for retail pharmacy services and supplies other than drug products.

Since publication of the Transactions and Code Sets rule, there has been ongoing debate in the industry about which is the appropriate standard for billing retail pharmacy supplies and professional services. Retail pharmacy supplies and professional services include syringes, applicators, inhalers and nebulizers, and home infusion IV supplies. These are often tied to a retail pharmacy claim for a prescription, such as insulin, ointments, and inhaler solutions. For example, a patient could get a prescription and/or refill for insulin and the syringes. Under the current rule, pharmacies are expected to submit the insulin claim in real-time, using the NCPDP standard, and get immediate benefit coverage and co-pay insurance information. However, they must bill the prescription for the syringes with the X12 standard, which

is typically a batch billing process so the pharmacist would not get immediate notification of coverage and co-pay insurance information. The transaction could be further complicated if the patient is prescribed consultation or Medication Therapy Management (MTM) services for the use and dosage of the insulin with the syringes. The issue of MTM is discussed later in this section.

At the time the Transactions and Code Sets rule was published, HHS' opinion that the NCPDP standard should be used for retail pharmacy and the X12 standard should be used for professional pharmacy claims was based on the inability of NCPDP to accommodate HCPCS codes that could be used to identify pharmacy procedures and services. The code set has since expanded, and Version 5.1 is now capable of accommodating the National Drug Codes (NDC) and the HCPCS codes to identify pharmacy procedures and services more accurately. In the Modifications rule (68 FR 8387), there was additional discussion regarding the complications of not allowing the use of NCPDP for pharmacy supplies and services, and there is significant discussion in that rule that supports the industry need to be able to use the NCPDP standard in place of the Version 4010 standard for these claims. Since publication of the Transactions and Code Sets rule and the Modifications rule, we have responded to substantial correspondence and provided guidance in a Frequently Asked Question (FAQ) clarifying that the NCPDP standard is to be used for billing retail pharmacy drug claims and that the X12 837 standard is to be used for billing retail pharmacy supplies and professional services. Nonetheless, there continues to be a lack of consensus in the industry regarding which standard to use for billing retail pharmacy supplies and professional services because of the disagreement as to what is a retail pharmacy drug claim. Some segments of the pharmacy industry interpret a retail pharmacy drug claim as one that could include pharmacy supplies and professional services, and therefore would permit the use of the NCPDP standard. Others believe that retail pharmacy drug claims do not include retail pharmacy supplies and professional services and, therefore, permit the X12 standard to be used. There are also entities that believe it is appropriate to use one or the other standard depending on whether the insurance benefit is medical, in which case X12 is used for retail pharmacy supplies and professional services, or whether it is a pharmacy benefit, in which case the NCPDP standard should be used. Whether the benefit is covered under medical or pharmacy is typically determined by the design of an employer's or health plan's benefit package. We also continue to receive input from the industry that it is common practice for pharmacies to use the NCPDP standard instead of the X12 standard because of the convenience and accuracy NCPDP provides for these services and claim types.

In 2006, the debate escalated due to implementation of the Medicare Part D Program under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). The MMA provides coverage for certain professional pharmacy services, referred to as Medication Therapy Management (MTM) services. MTM services are a distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision of a medication product. MTM encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. Some pharmacies believe it is appropriate to use the NCPDP standard for MTM services because the service is part of a prescription. Other segments, notably the small independent pharmacies, believe it is appropriate to use the X12 standard because they interpret ''professional services'' to mean that a ''professional'' (837P) claim is required and their vendor software offers that capability.

The industry acknowledges advantages and disadvantages for use of both standards, and has provided evidence that both standards should be considered compliant and that the use of either would be appropriate under HIPAA. In August 2007, a national organization sent a letter to CMS in support of using the NCPDP for both retail pharmacy service and supply type claims. The letter explained that chain drug stores feel strongly that they should be able to bill using NCPDP 5.1. Entities supporting the use of NCPDP 5.1 make the argument that NCPDP 5.1 offers real-time adjudication of claims, whereas the X12 837P is a batch process. According to the National Association of Chain Drug Stores, pharmacies are not coding for the X12 837 transaction because it is too cumbersome. Instead, when forced to use this transaction, pharmacies must use an outside vendor or clearinghouse, even though it is an added expense because they already have the capability to exchange the same information in real time with NCPDP 5.1. On the other side of the discussion, the independent pharmacies argue that X12 837 is the appropriate standard for ''supplies and professional services'' as evidenced by the fact that they have purchased software from their national association to accommodate this standard. Further, they believe that the X12 837 is more robust in its support of the data elements needed to bill for MTM services.

After discussions with representatives of national organizations as well as the NCPDP, CMS posted an addendum to its Frequently Asked Question (FAQ) on the CMS website in October 2007. This FAQ now also includes the following: ''While CMS adheres to its foregoing interpretation of the regulations requiring that MTM retail pharmacy services be reported using the X12 837P standard, we recognize that a reasonable argument could be advanced in response to the Department seeking to enforce this regulation, contending that the regulations could be read to instead direct the use of the NCPDP, Version 5.1 standard for such services. We further realize that notice and comment rulemaking, which the Department anticipates initiating in the near future will resolve the apparent ambiguity of these regulatory provisions. In light of the foregoing planned rulemaking and the uncertain outcome of any enforcement action, we elect not to take enforcement action against those covered entities that continue to use the NCPDP, Version 5.1 standard for this transaction.''

The implementation guides for both adopted standards accommodate the transaction, including the use of the appropriate code sets, and neither guide states clearly which standard applies for billing retail pharmacy services and supplies. This is a unique situation—no other HIPAA transactions can be adequately supported by two implementation guides. Based upon the input we have received from the industry on the use of these standards, we believe that allowing for the use of either the NCPDP or ASC X12 standards would accommodate prevailing business practices, ensure efficiency, and prevent redundant costs. For example, a pharmacy provider would no longer need to bill two separate claims (that is, one for a drug, and a separate claim for the supplies associated with the drug's administration). Health plans already accept both transaction types, and have the systems in place to adjudicate the retail and professional claims using either transaction. Therefore we do not believe this will be

an additional burden to plans. We do not believe that the proposed approach would be disruptive to current industry practice, as we have stated, and we do not believe that there will be any negative impact on providers or consumers in accommodating this existing business process. Rather, we believe our proposed approach would be the least disruptive to the industry because it accommodates prevailing business practices and permits entities to use the standard that is most appropriate, efficient and accurate for processing certain kinds of pharmacy transactions. Furthermore, the NCPDP standard accommodates the billing of supplies and services as well, if not more effectively than the X12 standard, because it was designed by the industry, with a specific focus on the full set of requirements for all types of pharmacy transactions. Both Version D.0 and Version 5010 accommodate the billing of supplies and services. This is also consistent with NCVHS recommendations dated June 17, 2004.

We solicit comments on the proposal to adopt both the NCPDP standard and the X12 standard for billing retail pharmacy supplies and professional services.

E. Modifications to the Descriptions of Standards

We propose to revise the descriptions of the transactions at § 162.1301, § 162.1401, and § 162.1501 to more clearly specify the senders and receivers of those transactions.

In the Transactions and Code Sets rule, we identified eight health care transactions and adopted standards for each of them. Included in most of the descriptions of those transactions is a specification of ''to whom'' and ''from whom'' the transaction is transmitted. This specification enables covered entities to be able to determine more easily when they may be conducting transactions for which a HIPAA standard is adopted and, therefore, when they need to comply with the transaction standard. However, descriptions for three of the transactions do not specify the ''to'' and ''from'' criteria—that is, the sender and receiver are not identified. This lack of specificity creates confusion and uncertainty in the industry about when a particular electronic transmission meets the definition of a transaction. In addition, in 2003 the Secretary's Advisory Committee on Regulatory Reform recommended that we adopt ''to'' and ''from'' data submission requirements for all of the standard transactions. We wish to make our existing policies as clear as possible, and we use this proposed rule as the opportunity to do so.

In this proposed rule, we would revise descriptions for three of the standard transactions to ensure that ''to'' and ''from'' requirements are specified.

1. Enrollment and Disenrollment in a Health Plan Transaction

In § 162.1501, the text does not specify the sender of the transmission. We propose to clarify, by revising the regulation text, that the enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information from the sponsor of the insurance coverage, benefits or policy to a health plan, to establish or terminate insurance coverage. The Version 5010 Implementation Guide also defines the transaction this way: ''The 834 is used to transfer enrollment information from the sponsor of the insurance coverage, benefits, or policy to a payer.''

We note that when enrollment and disenrollment information is currently sent electronically from a sponsor to a health plan, a sponsor that is not otherwise a covered entity is not required to use the transaction standard because, as a non-covered entity, HIPAA does not apply to it. A sponsor is an employer that provides benefits to its employees, members or beneficiaries through contracted services. Numerous entity types act as sponsors in providing benefits, including, for example, unions, government agencies, and associations. While it is not mandatory for plan sponsors that are not covered entities to use the transaction standard, such an entity may nevertheless voluntarily use the standard or may contract with a health care clearinghouse to translate nonstandard data into a standard transaction on its behalf in order to take advantage of available efficiencies and cost saving opportunities through EDI.

2. Referral Certification and Authorization Transaction

In § 162.1301, the text does not indicate who the senders and receivers of the referral certification and authorization transactions are—it simply states that the transmission is a request or response. We therefore propose to clarify the senders and receivers by stating that the referral and certification authorization transaction is any of the following transmissions:

- A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care.
- A request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider.
- A response from a health plan to a health care provider to a request described in the first or second bullet above.

3. Health Care Claim Status Transaction

In § 162.1401, the text does not indicate who the senders and receivers of the health care claim status transaction are—it simply states that the transmission is an inquiry or response. We therefore propose to clarify the parties to this transaction by stating that the health care claim status transaction is the transmission of either of the following:

- An inquiry from a health care provider to a health plan to determine the status of a health care claim, or
- A response from a health plan to a health care provider about the status of a health care claim.

F. Proposed Compliance and Effective Dates

We propose to revise § 162.900 to reflect that, for the Medicaid pharmacy subrogation transaction, all covered entities, except for small health plans, would be required to be in compliance no later than 24 months after the effective date of the final rule. Small health plans would have an additional 12 months for compliance. Willing trading partners would be able to agree to use the Medicaid subrogation standard voluntarily at any time after the effective date and before the compliance date. For example, covered entities that implement Version D.0 may choose to implement the Medicaid subrogation standard at the same time because such an action can be accommodated in the work flow.

CMS recognizes that transactions often require the participation of two covered entities, and when one covered entity is under a different set of compliance requirements, the second covered entity may be put in a difficult position. For the Medicaid subrogation of pharmacy claims transaction, small health plans would have an extra year to comply with the regulation. Therefore, if a Medicaid agency attempted to transmit Version 3.0 to a small health plan before the small health plan was required to be compliant, the small health plan could reject the transaction. This would require the Medicaid agency to use two versions of the transaction, or to use one compliant version, and one proprietary version, depending on the trading partner agreement with the small health plan for this interim period. We propose to resolve this problem of different

compliance dates by revising the language in § 162.923. Section 162.923, entitled ''Requirements for covered entities'' currently states, ''(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts with another covered entity (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.'' We propose to revise § 162.923 by making paragraph (a) applicable only to a covered entity that conducts transactions with another entity that is required to comply with the transaction standards. We believe that such a change would result in a less disruptive process by recognizing and resolving the difficult position covered entities may face when conducting transactions with trading partners who have different compliance deadlines. Accordingly, we would revise § 162.923 as follows: ''(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts with another covered entity that is required to comply with a transaction standard adopted under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.'' If we change § 162.923(a) in this way, a Medicaid agency, which would have a different compliance date than a small health plan with whom it is conducting the subrogation transaction, would not be required to conduct the transaction in the standard format until the date by which the small health plan must be in compliance with the standard.

We invite comments regarding the proposed compliance dates for our proposal to adopt the Medicaid pharmacy subrogation transaction standard. We further propose to revise section § 162.900 to remove the provisions related to the Administrative Simplification Compliance Act of 2001 (ASCA) Public Law 107–105.

The revised transactions descriptions would be effective on the effective date of the final rule.

NCVHS noted that, according to testimony, there were no expected implementation issues with Version D.0, but that implementation of Version 5010 would likely prove slightly more challenging because of the number of standards and the diversity of trading partners. However, because most covered entities will need to program for both Version 5010 and Version D.0, we believe that it is most practical to propose the same compliance dates for both. We propose that for Versions 5010 and D.0, health plans, including small health plans, health care clearinghouses and covered health care providers, be required to be compliant on and after April 1, 2010. We do not propose a 2-year time frame for compliance, as recommended by NCVHS, because we believe the industry has sufficient experience with implementation issues associated with the HIPAA standards to enable them to conduct their design/build activities, and schedule and perform testing within a 12-month period. Furthermore, the ability to implement and use the ICD–10 code set is contingent upon implementation of Version 5010. Since we anticipate timely publication of regulations to adopt the ICD–10 code set, we wish to give the industry sufficient time in which to effectively plan and implement the Version 5010 transaction standards. We anticipate the compliance date for ICD–10 to be in 2011. Presuming that, given this anticipated schedule, and in order to give the industry at least eighteen months of experience with Version 5010, the compliance date for those standards must be April 2010. We have not surveyed the industry broadly, other than the interviews conducted for the impact analysis, and while we acknowledge the logistical and implementation issues associated with the transition to Version 5010 and Version D.0, we maintain that the industry is capable of planning and designing the technical and operational infrastructure requirements in time for the proposed deadline. We believe that the benefits of the new versions, the potential for mitigating existing inefficient work arounds, and streamlining business processes will outweigh any benefits to be derived from a two-year compliance time frame recommended by the NCVHS. We specifically ask for industry comment on the timing and the costs of this proposed implementation schedule.

We also do not propose an additional year for small health plans to comply because we believe this allowance is unnecessary. Small health plans have had sufficient time to be compliant with the HIPAA transaction standards as well as the NPI, and to have made the appropriate investments in technology and infrastructure, as have their larger counterparts. The system and business process changes to accommodate Version 5010 and Version D.0 are not significant enough to warrant an additional year for those organizations that should now have sufficient experience with the standards.

We did consider, as an alternative, a proposal in which all health plans and all health care clearinghouses would be required to be compliant one year after the effective date, and covered health care providers would be required to be compliant 12 months later. In this way, providers would have ample time to test with their trading partners, and problems would be identified and resolved timely. We are not proposing the staggered compliance date option. Our discussion of the issues follows.

NCVHS testimony and subsequent industry input clearly support the adoption of Version 5010 for the affected X12 transactions and Version D.0 for the NCPDP transactions, but also confirm that it would be a significant undertaking for the industry, particularly in light of other potential Health IT initiatives such as migrating from the ICD–9 to ICD–10 code sets and implementing the new standards for claims attachments after that final rule is published.

The difficulties associated with implementation of the first set of HIPAA transaction standards and the National Provider Identifier (NPI) standard highlights the criticality of testing to ensure that transactions can be successfully exchanged between trading partners before the compliance date. The testing process is complex and time-consuming, especially for health plans and health care clearinghouses, which must test with very large numbers of trading partners. Historically, industry testing of the HIPAA standards has been concentrated at the very end of the compliance period, often resulting in insufficient time to identify and resolve all of the problems soon enough; this compression of the testing process has led to late identification of problems and has necessitated relief in the form of a flexible enforcement approach and contingency plans to avoid widespread noncompliance and cash flow disruption.

The July 2007 NCVHS letter, referenced earlier in this document, also recommended moving to a staggered compliance schedule for most of the standards proposed in this rule, which would require health plans and health care clearinghouses to be prepared for trading partner testing at the end of the first year of the implementation period, and to allow the second year to be used for testing. According to the NCVHS, this schedule would ensure that covered entities have ample time for communication, outreach, internal and external testing, corrective action, and

implementation. The NCVHS also recommended that CMS adopt certain levels of compliance for the standards. For example, Level 1 compliance would mean that the covered entity could demonstrate that it could create and receive compliant transactions. Level 2 compliance would demonstrate that covered entities had completed end-to-end testing with all of their partners.

Testing appears to be the key to successful timely implementation of standards. In fact, the NCVHS letter noted that testifiers emphasized that there was a need to test Version 5010 in real-life settings to ensure its interoperability and ability to support the transactions. Three types of testing needs were identified: (1) Testing of the standards for workability; (2) conformance testing of products and applications that send and/or receive the transactions; and (3) end-to-end testing to ensure interoperability among trading partners. NCVHS observed that, with the previous HIPAA transaction standards implementation, these three types of testing occurred unevenly, resulting in delays that could be minimized or avoided by staggering the various types of testing.

To accommodate an effective testing schedule, a variety of options for staggering the implementation of the Version 5010 and D.0 modifications were offered by testifiers to the NCVHS. There was a proposal to NCVHS that the compliance date for plans and clearinghouses could be a year before the date for providers in order to facilitate end-to-end testing. Alternatively, different compliance dates could be assigned to different transactions (for example, implement the claim and related transactions first). Testifiers at the July 30, 2007 hearings also attested to the importance of allowing dual processing (old plus new versions) for a sufficient period to allow end-to-end testing to occur.

Because of the importance of testing in achieving a smooth transition to the updated standards, we did consider proposing two different compliance dates for covered entities—a strategy in which health plans and health care clearinghouses would have to be compliant 1 year before covered health care providers to allow for adequate testing. However, such a proposal would shorten the overall implementation period for the entire industry and we believe it would present a number of other potential challenges to the industry.

First, a staggered implementation schedule would require all entities to use dual systems for the duration of the testing period, which could add to the cost of implementation, in part because plans and clearinghouses would have to implement a robust trading partner tracking system to know which providers were testing Version 5010, which were using Version 4010, and then, which successfully completed testing and had fully converted to Version 5010. Providers would have additional operational costs to manage their own testing and implementation schedule with plans and clearinghouses. The logistics could be complex, costly, and disruptive. Second, staggered compliance dates could impact plan-to-plan COB transactions because plans and providers would be implementing Version 5010 at different times. In order to conduct compliant Version 5010 transactions, all plans would have to be compliant at the same time, and all providers would have to be using Version 5010 as well, to take advantage of plan-to-plan COB. In addition, compliance in the case of a staggered implementation schedule would mean that, on the compliance date for plans and clearinghouses, those entities would have to be able to send and receive compliant transactions. However, it would be inappropriate to require plans and clearinghouses to reject noncompliant transactions received from providers during the one year period before providers would be required to be compliant, since the providers would not be required under this proposal to be able to conduct compliant transactions until the end of that period.

We believe we have the authority under the statute to propose different compliance dates for different entity groups, and we believe that exercising that authority could be in the interest of the industry to facilitate an orderly and effective transition to the use of the standards. However, for the reasons noted above, we are not proposing this approach. We are, however, interested in comments on the advantages and disadvantages of a staggered implementation schedule, specifically with respect to its effect on the testing process.

Although we are not proposing a staggered compliance schedule, we strongly encourage health plans and clearinghouses to begin to get their systems ready as early as possible, and providers to work with their trading partners to schedule testing timely as well. We also encourage clearinghouses and vendors to take advantage of the market opportunity to develop leading edge tools for implementing Version 5010, and support early testing for their provider clients. We note that NCVHS recognized the widespread use of compliance testing services, which allow entities to test products and applications to ensure they can create and accept compliant transactions. We agree that such services could simplify end-to-end testing by ensuring that individual products are compliant in advance. While HHS does not recognize or promote any specific organizations or tools for such services, we do support the use of such testing services for software and/or applications that would demonstrate a covered entity's ability to create, send, and receive compliant transactions.

We anticipate that upon publication of this proposed rule in the **Federal Register**, the industry will actively initiate and/or complete planning for implementation of Version 5010. While not included under the auspices of this proposed rule, we also acknowledge the impact of the implementation of the ICD–10 code set on the Version 5010 and Version D.0 implementation timelines. Once the Version 5010/Version D.0 and ICD–10 final rules are published, we estimate that the industry will begin documenting the requirements for the necessary system changes for each standard, initiate and/or complete any gap analyses, and then undertake design and system changes. The Version 5010/Version D.0 rule implementation would progress first, based on the need to have those updated standards in place prior to ICD–10 implementation in order to accommodate the increase in the size of the fields for the ICD–10 code sets. In the case of Version 5010 and Version D.0, system testing could commence approximately 8 months prior to a Version 5010 compliance date. We anticipate that ICD–10 testing could start shortly after the Version 5010 compliance date, and approximately one year prior to the October 2011 compliance date. Upon publication of these proposed rules for both Version 5010/Version D.0 and ICD–10 in the **Federal Register**, HHS, through CMS, plans on proactively conducting outreach and education activities, as well as engaging industry leaders and other stakeholder organizations to provide a variety of educational and communication programs to their respective constituencies. These activities would include roundtable conference calls with the industry, including Medicare contractors, fiscal intermediaries and carriers; health plans, clearinghouses, hospitals; physicians; pharmacies, other providers; and other stakeholders. CMS will also develop and make available ''Frequently Asked Questions'' on the website, fact

sheets, and other supporting education and outreach materials for partner dissemination. Other potential activities will be identified and developed based on stakeholder input.

The draft proposed timeline shown below is for preliminary planning purposes only, and represents our best estimate, given our current knowledge, of what an implementation timetable might look like. It is subject to revision as updated information becomes available.

DRAFT PROPOSED TIMELINE FOR ICD–10 AND VERSIONS 5010/D.0 IMPLEMENTATION

ICD–10	Version 5010/D.0
8/08: Publish proposed rule	8/08: Publish proposed rule.
	9/08: Industry begins requirements documentation for systems changes; CMS and industry initiate education and outreach.
12/08: CMS and industry begin ongoing education and outreach.	
	4/09: Industry builds and tests systems changes (internal and external testing).
06/09: Industry begins design documentation.	
12/09: Industry builds and internally tests systems changes.	
	4/10: Compliance date for all covered entities.
07/10–10/11: Conduct testing with trading partners.	
10/11: ICD–10 compliance date for all covered entities.	

We solicit industry and other stakeholder comments on our timeline assumptions and our proposed education and outreach strategy.

In sum, the challenges and difficulties encountered with previous standards implementation have informed the industry, which we believe now more meaningfully appreciates the benefits of collaboration, communication, and coordinated testing in making a substantial difference in successful implementation. Furthermore, we believe the industry is eager to move forward with Versions 5010 and D.0, and an aggressive timetable will be the right incentive to move the industry to proactive action and collaboration. We invite public comment on our proposed compliance dates.

III. Collection of Information Requirements

The burden associated with the information collection requirements contained in § 162.1102, § 162.1202, § 162.1301, § 162.1302, § 162.1401, § 162.1402, § 162.1501, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 of this document are subject to the PRA; however, these information collection requirements are currently approved under OMB control number 0938–0866. This package will be revised to incorporate any proposed additional transaction standards and proposed modifications to transaction standards not currently captured in the PRA package associated with OMB approval number 0938–0866.

IV. Response to Comments

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

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the proposed impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), as amended by Executive Order 13258 (February 26, 2002) and further amended by Executive Order 13422 (January 18, 2007), 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 further amended) 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). This proposed rule is anticipated to have an annual benefit on the economy of $100 million or more, and would have economically significant effects, making it a major rule under the Executive Order and the Congressional Review Act. We believe that covered entities have already largely invested in the hardware, software and connectivity necessary to conduct the new version of the standards, and the new standard proposed. We anticipate that the adoption of these new versions and the new standard would result in costs that would be outweighed by the benefits. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the proposed rulemaking.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires agencies to describe and analyze the impact of the proposed rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the health care sector, a small entity is one with between $6.5 million and $31.5 million in annual revenues or is a nonprofit organization. For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and

States are not included in the definition of a small entity. We have attempted to estimate the number of small entities and provide a general discussion of the effects of the proposed regulation, and where we had difficulty, or were unable to find information, we solicit industry comment. We believe that the conversion to Versions 5010 and D.0 would have an impact on virtually every health care entity, since at least some personnel in every covered entity would have to adjust to certain new business rules and procedures to accommodate the improvements in the data available from the transactions.

In our analysis, we combine Versions 5010 and D.0 because these two standards would be implemented at the same time, and in some cases are dependent on each other. For example, a health plan may use Version 5010 to send a remittance advice notification to a pharmacy, even though the pharmacy has used Version D.0 to submit its claim. This means that both the health plan and the pharmacy will have to implement both Version 5010 and Version D.0 in order to effectively exchange transactions. Similarly, a pharmacy may use Version 5010 to bill for supplies (for example, syringes), yet use Version D.0 for the retail pharmacy service of the insulin. The pharmacy will have to implement both Versions 5010 and D.0.

Table 27a in the impact analysis presents the implementation costs of Versions 5010, D.0 and 3.0 on all entities we anticipate would be affected by the rule. The data in that table are used in this analysis to provide cost information.

Because most health care providers are either nonprofit or meet the SBA's size standard for small business, we treat all health care providers as small entities. For providers, the changes may be minimal involving no more than a software upgrade for practice management and billing systems. Thus, we expect that the vast majority of physicians and practitioners will need to make relatively small changes in their systems and in their processes. We include pharmacies in this analysis, and consider some of them to be small businesses, and they are thus represented in our tables and the accompanying narrative. A number of health plans are considered small businesses, but we were unable to identify data for these entities, and therefore solicit industry feedback to complete this analysis for the final rule. We address clearinghouses and Pharmacy Benefit Managers (PBMs) in our discussion, but we do not believe that there are a significant number of clearinghouses that would be considered small entities because of the consolidation that has been occurring in the marketplace over the past 5 years. This was confirmed by a number of associations, including the Maryland Commission for Health Care. PBMs are excluded from the analysis because we have no data to indicate that they would qualify as a small entity. For example, as of 2006, the top four PBMs in the country accounted for about 75 percent of the prescription market, and of the top 10 PBMs, the largest showed revenues of more than $35 billion, with the smallest having revenues of $75 million (*http://www.managedcaremag.com/archives/0609/0609.pbms.html*). We invite comment and data from the industry regarding our assumptions.

State Medicaid agencies are excluded from this analysis because they have annual estimated revenues that exceed the small entity threshold of $31.5 million under the regulatory flexibility analysis guidelines. Furthermore, States are not considered small entities in any Regulatory Flexibility Analysis.

Initial Regulatory Flexibility Analysis (IRFA)

1. Number of Small Entities

In total, we estimate that there are more than 300,000 health care organizations that may be considered small entities either because of their nonprofit status or because of their revenues. On the provider side, practices of doctors of osteopathy, podiatry, chiropractors, mental health independent practitioners with annual receipts of less than $6.5 million are considered to be small entities. Solo and group physicians' offices with annual receipts of less than $9 million (97 percent of all physician practices) are also considered small entities, as are clinics. Approximately 92 percent of medical laboratories, 100 percent of dental laboratories and 90 percent of durable medical equipment suppliers are assumed to be small entities as well. The American Medical Billing Association (AMBA) (*http://www.ambanet.net/AMBA.htm*) lists 97 billing companies on its web site. It notes that these are only ones with Web sites.

The Business Census data shows that there are 4,786 firms considered as health plans and/or payers (NAICS code 5415) responsible for conducting transactions with health care providers. In the proposed rule's impact analysis, we use a smaller figure based on a report from AHIP. But for purposes of the RFA, we did not identify a subset of small plans, and instead solicit industry comment as to the percentage of plans that would be considered small entities.

We identified the top 78 clearinghouses/vendors in the Faulkner and Gray health data directory from 2000—the last year this document was produced. Health care clearinghouses provide transaction processing and translation services to both providers and health plans.

We identified nearly 60,000 pharmacies, using the National Association of Chain Drug Stores Industry Profile (2007, *http://www.nacds.org*), and for the purposes of the initial regulatory flexibility analysis we are proposing to treat all independent pharmacies reported in the Industry Profile as ''small entities.'' The number of independent pharmacies reported for 2006 is approximately 17,000 entities. We specifically invite comments on the number of small pharmacies.

Based on Figure 2 of the Industry Profile, independent pharmacy prescription drug sales account for 17.4 percent of total pharmacy drug sales of $249 billion sales for 2006. Allocating the 5010 and D.0 costs based on the share of prescription drug revenues to independent pharmacies (the small businesses), implementation costs are expected to range between $7.06 and $13.7 or 0.00 and 0.03 percent of revenues. These figures indicate that there is minimal impact, and the affect falls well below the HHS threshold, referred to at the beginning of this section.

2. Costs for Small Entities

To determine the impact on health care providers we used Business Census data on the number establishments for hospitals and firms for the classes of providers and revenue data reported in the Survey of Annual Services for each NAICS code. Because each hospital maintains its own financial records and reports separately to payment plans, we decided to report the number of establishments rather than firms. For other providers, we assumed that the costs to implement the 5010 would be accounted for at the level of firms rather than at the individual establishments. Therefore, we reported the number of firms for all other providers.

Since we are treating all health care providers as small entities for the purpose of the initial regulatory flexibility analysis, we allocated 100 percent of the implementation costs reported in the impact analysis for provider type. Table 1 shows the impact of the Version 5010 implementation costs as a percent of the provider revenues. For example, dentists, with

reported 2005 revenues of $87.4 billion and costs ranging from $299 million to $598 million have the largest impact on their revenues of between $0.19 percent and 0.39 percent. We are soliciting comments specifically on the number of providers affected by the proposed rule and information that will help us in our analysis of the burden on providers.

We do not include an analysis of the impact on small health plans here, because we were not able to determine the number of plans that meet the SBA size standard of $6.5 million in annual receipts.

In evaluating whether there were any clearinghouses that could be considered small entities, we consulted with three national associations (EHNAC, HIMSS and the Cooperative Exchange), as well as the Maryland Commission for Health Care, and determined that the number of clearinghouses that would be considered small entities was negligible. Revenues cited on the Cooperative Exchange Web site (*www.cooperativeexchange.org/faq.html*) divided clearinghouses into three revenue categories—small ($10 million); medium ($10 million to $50 million) and large ($50 million or greater). We identified the top 78 clearinghouses, and determined that they are typically part of large electronic health networks, such as Siemens, RxHub, Availity, GE Healthcare etc., none of which fit into the category of small entity. Finally, we contacted industry experts who have also been trying to gather revenue data from the industry without success. As referenced earlier, in a report by Faulkner and Gray in 2000, the top 51 entities were listed, and the range of monthly transactions was 2,500 to 4 million, with transaction fees of $0.25 per transaction to $2.50 per transaction. We determined that even based on this data, few of the entities would fall into the small entity category, and we do not count them in this analysis.

With respect to Version 3.0, we point out that while we do not know how many health plans/payers will exchange the subrogation standard with Medicaid agencies, those entities would be counted in the health plan category and addressed under the analysis for Version 5010 and D.0. We do not provide a separate analysis here.

In sum, we assumed that the financial burden would be equal to or less than three percent of revenues. HHS policy states that if a rule imposes a burden equal to or greater than three percent of a firm's revenues, it is significant (see: ''Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services'' at *http://www.hhs.gov/execsec/smallbus.html*). Based on the results of this analysis, we are reasonably confident that the rule will not have a significant impact on a substantial number of small entities. Nevertheless, we are specifically requesting comments on our analysis and asking for any data that will help us determine the number and sizes of firms implementing the standards proposed in this notice.

Table 2 below summarizes the impact of the rule on the health care industry.

TABLE 2—ANALYSIS OF IMPLEMENTATION OF THE BURDEN OF VERSIONS 5010, D.0 AND 3.0 ON SMALL COVERED ENTITIES

NAICS	Entities	Total Number of entities	Small entities	Revenue or Receipts ($ millions)	Small entity receipts of total receipts (in percent)	Version 5010/ D.0 annual costs (in millions)	Small entity share of version 5010/ D.0 Costs (in millions $)	Implementation cost revenue-receipts (in percent)
6221	General Acute Care Hospitals (establishments).	5,386	5,386	612,245	100	$536–$1,072	.....	0.09–0.18
6211	Physicians (firms)	189,562	189,562	330,889	100	250–501	.....	0.08–0.15
6212	Dentists (firms)	118,163	118,163	87,405	100	172–344	.....	0.19–0.39
44611	Pharmacies (includes 5010 and D.0)	56,946	17,482	249,000	17.4	49–96	7.1–13.7	0.02–0.03

In column 1 we display the NAICS code for class of entity. Column 2 shows the number of entities that are reported in the Business Census for 2006 or ''Chain Pharmacy Industry Profile.''

Column 3 shows the number of small entities that were computed based the Business Census and Survey of Annual Service when the data was available. All health care providers were assumed to be small. We assumed that all independent pharmacies reported in Table 2 of the Industry profile are small entities.

Column 4 shows revenues that were reported for 2005 in the Survey of Annual Services, or in the case of pharmacies, in Figure 2 of the Industry profile. In the case of health plans and third party administrators, we used the consumer payments reported for private health insurance in 2006 in the National Health Expenditure accounts.

Column 5 shows the percent of small entity revenues.

Column 6 shows the implementation costs for Version 5010, D.0 and 3.0 taken from Table 27a of the impact analysis.

Column 7 shows the costs allocated to the small entities based on the percent of small entity revenues to total revenues.

Column 8 presents the percent of the small entity share of implementation costs as a percent of the small entity revenues. As stated in the guidance cited earlier in this section, HHS has established a baseline threshold of 3 percent of revenues that would be considered a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold.

We note that the impact in our scenarios is consistently under the estimated impact of 3 percent for all of the entities listed above, which is below the threshold the Department considers as a significant economic impact. As expressed in the Department guidance on conducting regulatory flexibility analyses, the threshold for an economic impact to be considered significant is 3 percent to 5 percent of either receipts or costs. As is clear from the analysis, the impact does not come close to the threshold. Thus based on the foregoing analysis, we conclude that some health care providers may encounter significant burdens in the course of converting to the modified Versions 5010 and D.0. However, we are of the opinion that, for most providers, health plans, and clearinghouses the costs will not be significant.

3. Alternatives Considered

As stated in section V.D of this proposed rule, we considered various policy alternatives to adopting Versions 5010, D.0 and 3.0. For Version 5010, one alternative considered was that we not adopt the modifications, but allow the industry to continue using the current versions. This would not have been an appropriate solution because it does

nothing to address the existing shortcomings of the current versions, such as issues with inconsistent instructions, situational rules that preclude the full benefits of standardization for the industry, limited eligibility and secondary payer information, and continued reliance on companion guides from health plans. The existing shortcomings of the currently adopted standards continue to impact the industries' ability to meet evolving business needs and advanced technology.

We considered a number of options for implementing a staggered transition to Version 5010—phasing in the implementation of the new standards by covered entity type. For example, clearinghouses and health plans would modify their systems first, followed by providers. We rejected this option as being too costly and too burdensome. This option would require clearinghouses and health plans, which are largely national, covering multiple states, to maintain and operate both Version 4010/4010A and Version 5010. Programmers would have to accommodate the new standards, but maintain programs for the older version. This could increase the likelihood of errors in payments and incorrect eligibility information, and could create confusion and uncertainty for providers. It is likely that there would be delays in claims processing. We believe the cost of maintaining two systems concurrently would impose a very significant burden on health plans, providers, and clearinghouses.

Another alternative considered and rejected was to delay implementation for small entities. However, because we treat all health care providers as small entities, we did not see any benefit to be gained from delaying implementation of Version 5010 beyond the 18 month implementation period being proposed in the rule, and therefore rejected this alternative.

A final alternative considered was waiting and adopting later versions of the X12 standards. In large part, this is not a feasible option since the adoption of Version 5010 is critical to the use of ICD–10. Given our expectation that use of the ICD–10 code set will be mandated in the next few years, the industry must have experience using Version 5010 in order to effectively implement ICD–10. We recognize that other relevant Federal Rules, current or future, may overlap and/or affect this proposed rule. We do not believe that this proposed rule conflicts with the expected ICD–10 rule, but rather supports the industry's ability to implement that code set in a more timely fashion.

We considered various alternatives to adopting NCPDP Version D.0. One alternative that was considered but not proposed was to do nothing and keep the current Version 5.1 as a HIPAA transaction standard. This option, however, would not support the health care industry's needs for better and enhanced claims information. If the Department continues to require Version 5.1, the enhancements that were made in Version D.0 to improve Part D eligibility and claims processing would put those who rely on this information at a disadvantage.

Another alternative we considered was to stagger the implementation dates for the Version D.0 among the entities that utilize the affected NCPC transaction. This alternative is not feasible since pharmacies, PBMs, and health plans all rely on the information transmitted though the NCPDP transaction. If any one of these three entities is not using the same NCPDP version at the same time, the information needed to process claims and check eligibility would be deficient. Pharmacies need the most current eligibility data from the plans to determine correct coverage and payment information. Plans and PBMs would suffer because they would not have the most current information reflected though the claims data to maintain the beneficiaries' most current benefits.

We considered a number of alternatives to proposing the adoption of the NCPDP 3.0 Medicaid pharmacy subrogation standard. We considered not adopting the standard, which would allow the industry to continue using Version 2.0 or other proprietary electronic and paper formats. This option would mean that the Medicaid plans would have to continue to support multiple formats in order to bill pharmacy claims to third party payers. The current multiplicity of claim formats creates a significant barrier to Medicaid agencies being able to comply with Federal law in ensuring that Medicaid is the payer of last resort.

We also considered adopting the Version 2.0 standard which would require a number of workarounds to be compatible with Version D.0 or other NCPDP claim standards (except for NCPDP, Version 5.1). The NCPDP testified to the NCVHS in January 2008 that adopting Version 3.0 for Medicaid subrogation is a cost-saving tool and will improve the efficiency of those already using Version 2.0. The NCPDP testified that adopting Version 3.0 will make it more feasible for states and payers to invest in system upgrades to accommodate one specific standard. The NCVHS did not recommend any viable alternatives to Version 3.0 for handling Medicaid subrogation transactions because it believes that Version 3.0 adequately addresses the business needs of Medicaid agencies and industry partners.

4. Conclusion

As stated in the HHS guidance cited earlier in this section, HHS uses a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold. Based on the foregoing analysis, we could certify that this proposed regulation would not have a significant economic impact on a substantial number of small entities. However, because of the relative uncertainty in the data, the lack of consistent industry data, and our general assumptions, we invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the various categories of entities affected by the proposed rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would affect the operations of a substantial number of small rural hospitals because they are considered covered entities under HIPAA and must comply with the regulations; however, we do not believe the rule would have a significant impact on those entities, for the reasons stated above in reference to small businesses. Therefore, the Secretary has determined that this proposed 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 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold is approximately $130 million. This proposed rule contains proposed mandates that would impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, in excess of the current

threshold. This impact analysis addresses these impacts both qualitatively and quantitatively. In general, each State Medicaid Agency and other government entity that is considered a covered entity would be required to invest in software, testing and training to accommodate the adoption of the modified versions of the standards, and the new standard. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from (A) imposing enforceable duties on State, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

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. This proposed rule would have a substantial direct effect on State or local governments, could preempt State law, or otherwise have a Federalism implication because even though State Medicaid agencies would be converting to a modified version of an existing standard (Version 4010/4010A to Version 5010 and NCPCP 5.1 to NCPDP D.0) with which they are already familiar, there are expenses for implementation and wide-scale testing. State Medicaid agencies are currently required to conduct pharmacy subrogation, and in accordance with this proposed rule, would be able to use either the new Medicaid pharmacy subrogation standard or contract with trading partners and/or contractors who specialize in this field to fulfill its subrogation requirement, but there would still be some level of implementation costs to bear. With respect to subrogation for pharmacy claims, we note that this proposed rule would not add a new business requirement for States, but rather would mandate a standard to use for this purpose which would be used consistently by all States. There will also be expenditures for States as they convert from Version 5.1 to D.0 for other pharmacy transactions, and this transition will have implementation and testing costs as well, meaning there will be additional fiscal impacts on States based on this rule.

C. Anticipated Effects

The objective of this regulatory impact analysis is to summarize the costs and benefits of the following proposals:

- Migrating from Version 4010/4010A to Version 5010 in the context of the current health care environment;
- Migrating from Version 5.1 to Version D.0; and
- Adopting a new standard for the Medicaid subrogation transaction.

We assume for purposes of this analysis that maintaining existing practices with respect to claims submissions for retail pharmacy supplies and services (as discussed in section II.D above) would have no impact on the industry.

The remainder of this section provides details supporting the cost benefit analysis for each of the three above-referenced proposals.

1. Adoption of Version 5010

This portion of the analysis is based on industry research conducted for us by Gartner, Incorporated (Gartner) to assess the costs and benefits associated with the adoption of Version 5010. As part of this endeavor, Gartner worked with us to establish a segmentation strategy to identify the individual segments across the full spectrum of health care that would be affected by the proposed migration to Version 5010. These segments were identified:

Providers

- Hospitals
- Physicians
- Dentists
- Pharmacies

Health Plans

- Commercial Health Plans and Blue Cross/Blue Shield Plans
- Government Plans: Medicare and Medicaid

Clearinghouses and Vendors

- Clearinghouses
- Vendors

Based on this segmentation, Gartner identified and interviewed select credible individuals with representative perspectives. These individuals addressed both the business and technical areas for their respective organizations or associations, and were capable of understanding and articulating the potential cost-benefit of changes to their existing systems and processes. In addition to these interviews, Gartner conducted research to complement the existing data on the current state of HIPAA transactions. This research included dialog and data collection from leading associations and other stakeholder constituencies that represented one or more of the segments identified. We note that we did not interview any ''non-hospital'' institutions, but made the assumption that skilled nursing facilities (SNFs) and other types of organizations may be affiliated with some of the larger hospital systems, which were included in the analysis. Furthermore, we have not broken the data out to reflect any particular sub-segment of the industry, other than hospitals, physicians, dentists and pharmacies. The benefits were based on the total number of all claims throughout the health care system, including non-hospital institutions. We believe that while not all possible organization types were interviewed, the assumptions and findings can be extrapolated to provide fair insight into the financial impacts across the industry. This applies to any federal agency that must comply with the rule; these entities will have similar costs and benefits to their private sector cohorts. We invite public comment and cost or benefit data to support any concerns about the accuracy or consistency in our assumptions and estimates, particularly related to non-hospital institutions.

Throughout this process, Gartner constructed a cost-benefit model that synthesized the findings from the interviews as well as the inputs from the secondary research. This model was developed to estimate the net impact of implementing Version 5010 across the entire health care spectrum inclusive of all of the individual segments. When the model was completed, Gartner conducted a series of internal quality assurance steps, a sensitivity analysis, and peer review to properly validate the results.

Affected Entities

All HIPAA covered entities would be affected by this proposed rule. Covered entities include all health plans, all health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard. We note that health care providers may choose not to conduct transactions electronically. Therefore, they would be required to use these standards only for transactions that they conduct electronically. See the Transactions and Code Sets rule for a discussion of affected entities (65 FR 50361).

Covered entities would incur a number of one-time costs to implement Version 5010. These costs would include analysis of business flow changes, software procurement or

customized software development, integration of new software into existing provider/vendor systems, staff training, collection of new data, testing, and transition processes. Systems implementation costs would account for most of the costs, with system testing alone accounting for 60 to 70 percent of costs for all covered entities. Ongoing operational costs are expected to initially grow as transmissions increase, but would result in lower costs per transaction as higher volumes are handled. The costs would be offset by the benefits of increased Electronic Data Interchange (EDI) and operational savings.

Through the interview process, Gartner estimated the cost of implementing Version 5010 by establishing an estimated baseline cost for implementing Version 4010/4010A for each individual entity. Subsequently, it determined the comparative costs for Version 5010 as a percentage of the total estimated Version 4010/4010A costs. Since the costs of implementing Version 4010/4010A are now more quantifiable, this methodology provided the most reliable means of estimating the Version 5010 costs. Most sources agreed that Version 5010 costs would represent 20 to 40 percent of the total cost of implementing Version 4010/4010A. This is because the Version 4010/4010A implementation represented a shift to completely new standards, while Version 5010 is a less complex move from one version of a standard to another. Most start up investments, such as hardware procurement made during the Version 4010/4010A implementation, would not need to be repeated for Version 5010. The estimated total cost for implementing Version 4010/4010A during its 2 year implementation period for each segment is: $4,661 million for hospitals; $2,175 million for physicians; $1,493 million for dentists; $336 million for pharmacies; $18,021 million for private plans/health plans: $1,202 million for government plans and $125 million for clearinghouses. In calculating the minimum and maximum costs for implementing Version 5010, the 20 and 40 percent ranges have been applied to each of the minimum and maximum estimates for implementing Version 4010/4010A, except for pharmacies. In analyzing cost projections for the pharmacy industry, we use an estimate of 20 percent because, as will be explained below, some portion of the implementation costs would be addressed by the pharmacy efforts to comply with Version D.0.

The current limitations of Version 4010/4010A and anticipated benefits of Version 5010 are discussed in detail in Section II.A. This cost benefit analysis considers those anticipated benefits in analyzing how affected entities would convert to key financial and business advantages, including:

- Lower transaction costs resulting from movement from paper to electronic transactions and;
- Reduction in staff resource time resulting from a decrease in phone calls to check eligibility and claim status and obtain referral authorizations via electronic transactions that provide the same information;

Gartner estimated the benefits of implementing Version 5010 by identifying three specific categories of savings: (1) Savings due to better standards for electronic claims transactions; (2) cost savings due to an increase in use of the electronic *claims transactions* by more covered entities; and (3) operational savings due to increased use of electronic auxiliary transactions by more covered entities. We refer to auxiliary transactions as those non-claims electronic transactions such as eligibility and referral requests and responses. The savings categories are further described as follows:

- Savings due to better standards—increased use of the electronic claims transactions resulting in a decreased need for manual intervention
- Cost Savings—increased use of claims related electronic transactions by entities that had not used them before (remittance advice, claims status)
- Operational Savings—increased use of auxiliary, non-claims electronic transactions by entities that had not used them before (eligibility requests and responses).

Each savings category is explained in more detail in the assumptions section below and we encourage readers to refer back to this assumptions section during the review of the cost benefit analysis.

All financial analysis is calculated over a 10-year planning horizon, including an assumption that there would be a 2-year implementation period. System implementation costs are assumed to be incurred over that 2-year implementation period and are distributed evenly in our analysis. Benefits are assumed not to be realized until post-implementation, in 3 to 10 years.

Assumptions for Version 5010 Impact Analysis

In calculating the costs and benefits, Gartner made a number of assumptions, based on interview data and secondary research. The interviews provided information that was used to reflect the size of the industry segments, the segment implementation costs, and the application of benefits and savings. We provide those assumptions and estimates here for reference throughout this portion of the impact analysis. We are specifically soliciting comments on the assumptions related to costs and benefits, as they are presented in this section of the proposed rule.

In Table 2 below, we show the projected annual claims volumes for providers over a ten-year period. Gartner projected the annual increase in the number of claims at four percent, and used the base from the estimates that were identified in the Claims Attachments proposed rule. These figures are used as a base to calculate the provider benefits.

TABLE 2—ANNUAL CLAIM VOLUME PROJECTIONS (IN MILLIONS)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Physician (low)	3,186	3,313	3,446	3,583	3,727	3,876	4,031	4,192	4,360	4,534
Physician (high)	4,142	4,307	4,480	4,659	4,845	5,039	5,241	5,450	5,668	5,895
Hospital (low)	796	828	861	896	932	969	1,008	1,048	1,090	1,134
Hospital (high)	1,036	1,077	1,121	1,165	1,212	1,260	1,311	1,363	1,418	1,475
Dentist (low)	540	561	584	607	631	657	683	710	738	768
Dentist (high)	660	686	713	742	772	802	834	868	903	939
Total claims (low)	4,552	4,702	4,891	5,086	5,290	5,501	5,721	5,950	2,264	6,607
Total claims (high)	5,837	6,071	6,314	6,566	6,829	7,102	7,386	7,681	7,989	8,309

Table 3 below reflects the estimated current adoption rate for each of the HIPAA standards, and the projected rate of adoption for each of the modified versions of the standards over the 10-year planning horizon. For the enrollment (834) and payroll deducted and other group premium payment (820) standards, we assume utilization would apply only to health plans since providers do not use either of these two standards. We assume that acceptance rates would gradually increase in the first 5 years after implementation, through 2016, and after that time would remain level.

TABLE 3—CURRENT AND PROJECTED RATES OF USE FOR HIPAA STANDARDS ACROSS ALL COVERED ENTITIES—OVER 10 YEARS [IN PERCENT]

Standard	Current Acceptance	Increase (minimum)	Increase (maximum)
837—claims	75	2	5
835—remittance advice	60	5	10
278—referral request & response	**0	10	20
276/277—claims status request & response	10	10	20
270/271—eligibility request and response	10	10	20
834—enrollment/disenrollment	3	0	0
820—premium	2	0	0

Source: Gartner interviews and secondary research.
** Minimal use—while there is not quite zero percent uptake, the use of this transaction is so minimal, it does not register on any scale; therefore, we state its current acceptance rate as negligible.

General Assumptions for the Cost-Benefit Analysis for Providers and Health Plans

For the cost benefit analysis for each of the provider segments—hospitals, physicians, pharmacies, and dentists as well as the health plans, we apply the following set of assumptions, which are listed below. (These assumptions will not be repeated in each individual section of the impact analysis to follow.) Benefits that would accrue to each provider segment include:

- All providers currently using 835/837 messages would accrue benefits in the way of savings (for example, through reduced phone calls).
- Physicians that have not yet implemented 835/837 would accrue future savings through lower transaction costs for these electronic exchanges.
- An expected uptake of between 2–5 percent in the first five years following implementation, for all providers implementing 837 transactions (for example, 75 percent in 2010; 77 percent in 2015).
- An expected uptake of between 5–10 percent over ten years for all providers for 835 transactions.
- Costs and benefits for the Coordination of Benefit transaction (COB) are included in the estimates for the 837 claim standard transaction and are not broken out separately.
- Providers would benefit from fewer phone calls to health plans to check eligibility or claims status for auxiliary transactions (270/271, 276/277, 278).
- An expected increase in the usage of auxiliary transactions across the entire provider community and new adopters would see net benefits that would compound the aforementioned benefits as adopters utilize EDI more often.

The operational savings would result from reductions in manual efforts, particularly phone calls that must be made to resolve issues with a transaction that is manual today, such as a claim status or eligibility check. Each phone call avoided for a claim transaction is estimated to save 10 minutes of time for a provider's staff member, and each required manual intervention avoided is estimated to save 5 minutes of time. The following are estimates of the potential volume of avoided phone calls for providers:

- 835—A reduction in phone calls between 1.45 percent and 2.90 percent as a percentage of pended claims. This would equate to millions of phone calls for providers in the first year with increasing amounts in subsequent years as claim volumes increase.
- 837—A reduction in phone calls between 0.28 percent and 0.70 as a percentage of pended claims. This also would equate to millions fewer phone calls for all providers.
- For all other transactions, the current call volume would be reduced proportional to their total transaction volume. Because of the smaller volumes for these transactions, the additional savings was deemed to be too small for inclusion into the overall model.

Cost savings from reduced phone calls were estimated based on annual loaded compensation for plan or provider staff members (customer service, claims or billing) at $40,000 and billing/claims resources at $60,000 which equates to $0.32 per minute and $0.48 per minute respectively.

As a corollary to the operational and uptake benefits identified for the providers, health plans would expect corresponding benefits including:

- For 835/837 messages, plans would receive benefits in the way of savings through reduced phone calls related to ambiguity in the current messages.
- As uptake of the 835/837 transactions increase between trading partners, there would be savings through lower transaction costs; in other words, unit costs would decrease.
- For auxiliary transactions (270/271, 276/277, 278), plans would receive benefit in the way of operational savings through reduced phone calls.

Since we would expect an increase in the market for auxiliary transactions within the physician community as new uptake occurs with trading partners, plans would receive some cost savings through lower transaction costs.

Explanation of Cost Calculations

To determine the costs for each subsegment (that is, hospitals, physicians, and dentists), we established an estimate for what the total approximate Version 4010/4010A costs were for an individual entity within that subsegment (based on the interviews and other data available through research) and then applied an estimated range of 20 to 40 percent of those costs to come up with estimated minimum and maximum costs for Version 5010. The range was accepted as a realistic proxy by all providers and plans who participated in the interviews. Through the course of the interviews, we identified more granular cost categories and reviewed these with the participants to help analyze and validate overall cost estimates by entity.

Table 4 below shows Gartner's estimates of costs for Version 4010/

4010A implementation, which again, were calculated based on estimates of implementation for each individual entity within a segment, and multiplying that estimate by the number of entities.

TABLE 4—GARTNER ESTIMATED TOTAL COST FOR IMPLEMENTATION OF VERSION 4010/4010A

Segment	Costs (in millions)
Hospitals*	$4,661
Physicians	2,175
Dentists	1,493
Pharmacy	336
Private Plans	18,021
Government Plans	1,202
Clearinghouses	125

Source: Gartner interviews and secondary research.

*Includes some long term care and skilled nursing facilities when connected to a hospital or hospital system.

Table 5 reflects our assumptions regarding the percent of the total costs allocated to each cost category (for example, testing and training) for the provider and plan segments. Specifically, we estimated that 60 percent of all implementation costs would go towards testing for providers, and 70 percent for plans. We invite comment from the industry on these assumptions and estimates, particularly on the assumption that there would be no new hardware costs for implementing Version 5010, since the interviews did not yield information on providers who do not currently have electronic capability.

TABLE 5—PERCENTAGE AND TOTAL AMOUNTS FOR COST ITEMS USED FOR VERSION 5010 CALCULATIONS—PROVIDERS AND HEALTH PLANS

Cost item	Percent of total costs	
	Providers	Health plans
Hardware Procurement	0	0
Software Costs	15	10
Transmission Costs	0	0
New Data Collection	0	0
Customized Software Development	5	2.5
Testing Cost	60	70
Training Costs	5	2.5
Transition Costs	15	15
Totals	100	100

Source: Gartner interviews and secondary research.

Transition costs, which we assume will occur in the third year of implementation, are defined as the post-implementation costs for monitoring, maintaining, and adjusting the upgraded systems and related processes with trading partners until all parties reach a ''steady state.'' An example of this type of cost might be additional bug fixes and the associated testing required on the Version 5010 platform after the system has been fully cut over. In addition, some interviewees expected there to be some laggards in implementing Version 5010 after the regulation timeline and expected to incur additional costs during this transition period as a result of late entrants. We note that we do not include hardware costs even for providers who might move from a paper-based system to an EDI system because we do not believe that the number of providers who have no electronic capability is very high. We do believe that providers who move away from a paper-based system are likely to have software and/or vendor costs, and we account for this. We invite stakeholder comment on these assumptions, and welcome any data regarding the number of providers who do not have any hardware to support electronic transactions.

Explanation of Benefits and Savings Calculations

In our analysis, we assume that benefits would accrue in three categories which arise from: (1) Better standards—improvements in the claims standards which would increase their usability and reduce manual intervention; (2) an increase in the adoption and use of the electronic claim transactions themselves, which would result in financial savings through an increased use of EDI; and (3) an increase in use of the auxiliary transactions, such as eligibility, claims status, and referral, which would reduce manual intervention (personnel involvement) and increase efficiencies and cash flow. For ease of understanding, we label the three savings categories as Better Standards, Cost Savings and Operational Savings, though all three represent savings to the entities. We further explain each category again here, and include the ''titles'' we have given them:

(1) Better standards or savings due to improved claims standards: The improvements in Version 5010 that would reduce manual intervention to resolve issues related to the claim or remittance advice, due to ambiguity in the standards;

(2) Cost savings or savings due to new users of claims standards: Increased use of electronic transactions for claims and remittance advice that would accrue to parties who had previously avoided the electronic transactions because of their deficits and shortcomings; and

(3) Operational savings or savings due to increased auxiliary standards usage: Increase use of auxiliary transactions through EDI that would result from a decrease in manual intervention to resolve issues with the data (handled through phone calls or correspondence).

To calculate the savings in the ''better standards'' savings category, which is specific to the increased use of electronic transactions for claims and remittance advice, we use data from a 2007 report compiled by America's Health Insurance Plans (AHIP) which indicated that savings due to EDI were in the range of $.73 per transaction. Using the $.73 as the baseline, Gartner used the interviews to refine this estimate for both providers and plans. We apportion the amount between providers and plans, and based on the interviews, anticipate that providers would receive at least $.55 in savings for moving transactions from paper to EDI and plans would benefit by at least $.18. All of the operational benefits were based on reduced phone calls and manual intervention as a percentage of total claims. Because we do not have any concrete numbers for how many claims the private plans process versus the government plans, we used the percentage of covered lives as stated in the Harvard/JFK School of Public Policy study as the best way to approximate how much of the benefits would go to private plans versus government plans (82 percent covered lives in private plans versus 16 percent for government plans) (Harvard JFK School of Public Policy—''Health care delivery covered lives—Summary of Findings—2007'') We further assumed that there are no material differences in the number of claims handled with the government-covered lives versus private-covered lives.

Table 6 details the business activities such as manual interventions and phone

calls that make up the calculations for the other two categories of projected savings: Cost and operational savings related to an increase in users of the electronic transactions for claims, and an increase in use of the auxiliary transaction standards by all covered entities. Where we speak of ''manual intervention,'' we mean that a human resource must take some action related to a particular claim or inquiry because the transaction has been delayed, pended or rejected.

Calculations are based on the number of interventions and the amount of time spent per intervention, multiplied by the average cost per intervention (based on average salaries for certain full-time employees). Affected entities can use the categories and calculations shown here to compare against their own operations, in order to evaluate the proposed impact to their own organization.

Based on industry interviews, we identified the average annual compensation packages, amount of time for certain business activities (manual interventions) related to claims and other transactions, and determined the cost per minute for these activities. According to Gartner's interviews, and for purposes of this analysis, we estimate the average annual compensation package (salary plus benefits) for a health plan or plan service representative to be $40,000 and for a provider billing specialist to be $60,000. The cost per minute for a service representative is $0.32 ($40,000/(2080*60)) and for a provider representative is $0.48. We invite industry comment on these estimates.

TABLE 6—PHONE CALLS AND MANUAL INTERVENTIONS REQUIRED BY PROVIDERS AND HEALTH PLANS DUE TO LACK OF EDI OR NON USE OF EDI

Industry segment	Amount of time
Providers:	
Time taken by a provider billing agent to process manual intervention for a pended claim.	10 minutes. Example: 10 minutes × .48 = $4.80 per call
Time taken by a provider billing agent to process non Auto adjudicated claims.	6 minutes.
Time taken by a provider's office staff member to find out Eligibility information.	5 minutes.
Time taken by a provider billing agent to find out the status of the claim	12 minutes.
Time taken by a provider's office staff member to find out the status of a referral.	10 minutes.
Health Plans:	
Time taken by a plan claims processor to process manual intervention for a pended claim.	5 minutes.
Time taken by a plan claims processor to process non Auto adjudicated claims.	5 minutes.
Time taken by a plan customer service representative to give eligibility information.	5 minutes.
Time taken by a plan customer service representative to give status of the claim pended claim.	8 minutes.
Time taken by a plan Utilization Review representative to give status of a referral.	8 minutes.

Source: Gartner interviews and secondary data.

The formulas for the three savings categories are as follows:

(1) Better standards: Number of estimated claims transactions (835/837) requiring a phone call times the number of minutes per call, times the average cost per minute (for example: 1,000 claims × 10 minutes × $0.48 = $4,800)

(2) Cost savings (new use of EDI for 835/837): Number of transactions converted from paper to EDI (estimated to have a range of 2 to 5 percent over 10 years) times estimated cost savings per transaction (total savings of $0.73, where the provider benefit is $0.55 and the plan benefit is $0.18).

(3) Operational savings for increased use of EDI for auxiliary transactions: Number of estimated transactions (for the 270/271, 276/277, 278) requiring a phone call times the number of minutes per call times the average cost per minute. For example: 1,000 transactions × 10 minutes × 0.48 = 4,800.

Other data points of relevance to this analysis include the number of health care claims exchanged between covered entities. Based on its research, Gartner assumed a low estimate of 4,522 million and a high estimate of 5,837 million claims annually, beginning in 2010. Table 7 depicts the percent of transactions that are electronic, and their disposition. Gartner also assumes that 14 percent of all claims annually are pended, meaning that they are not paid upon receipt, and may be held for additional information.

TABLE 7—DISPOSITION OF CLAIMS TRANSACTIONS

	Percent
Electronic Claims	75 percent.
Auto Adjudication of electronic claims	71 percent.
Pended claims	14% (of all claims).
Cost savings from electronic transactions	$0.73 ($0.55 for providers; $0.18 for plans).

Source: AHIP Report: ''An Updated Survey of Health Care Claims Receipt and Processing Times,'' May 2006.

1. Health Care Providers

As discussed above, providers are covered entities under HIPAA if they transmit health information in electronic form in connection with a HIPAA transaction. Providers are not required by HIPAA to conduct transactions electronically, but if they do, they must use the HIPAA standards adopted by the Secretary. However, Medicare providers, with a few limited exceptions, are required to submit Medicare claims electronically under the Administrative Simplification Compliance Act of 2001 (ASCA) Public Law 107–105. Providers may conduct the following transactions: Health care claims or equivalent encounter information, health care payment and remittance advice, eligibility for a health plan, referral certification and authorization, and health care claim status. They do not conduct the enrollment and disenrollment in a health plan or health plan premium payment transactions. Many providers submit claim transactions electronically, and somewhat fewer accept electronic remittance advices. Usage of the auxiliary transactions (eligibility, claim status, and referral/authorization) is much lower than the claims transactions.

Providers that conduct a transaction electronically would be required to implement Version 5010 of that transaction. As stated, we assume that the improvements in Version 5010 would result in more providers conducting those transactions electronically. Use of the claims transaction (837) is already high for providers and would be moderately affected by improvements in Version 5010. While the 835 remittance advice is also used, there are a number of technical issues that have hampered its wide-scale deployment. These issues were discussed in the preamble of this proposed rule. Utilization overall would increase due to the technical improvements in Version 5010. More providers will use any or all of the non-claims electronic transactions because the improvements will make them more useful. The auxiliary transactions for eligibility, claims status and referrals currently have relatively low utilization under Version 4010/4010A because of the perceived lack of business value. We believe adopting these modifications will change that trend. For example, the Version 4010/4010A eligibility transaction only requires that minimum data about an individual patient and his/her coverage be returned on the response, and that minimum data set is not useful to providers. Thus, very few providers or health plans have implemented this transaction, preferring instead to use existing voice and interactive voice response (IVR) systems. Improvements in the Front Matter section and instructions for Version 5010 would yield a modest increase in use, which would have a positive financial impact on providers and health plans. Our assumptions regarding the providers' current acceptance of the transactions and the projected adoption rate are shown in Table 2 in the assumptions section. In the remainder of this section, we discuss the costs and benefits of implementing Version 5010 for each segment of the provider industry, including hospitals, physicians, pharmacies and dentists.

a. Hospitals

For purposes of this cost/benefit analysis, hospitals were divided into three categories based on bed-size (See table 8 below).

TABLE 8—HOSPITAL BREAKDOWN

Hospital size	Number of hospitals
400+ Bed Hospitals	521
100–400 Bed Hospitals	2,486
Fewer than 100 bed hospitals	2,757
Total	5,764

Source: AHA Hospital Statistics 2007 edition.

Hospitals have pursued various implementation models of the HIPAA standards, including Direct Data Entry (DDE), internally managed EDI, use of clearinghouses or billing vendors, and a variety of hybrids of these models. All of these implementation models were considered in this analysis. Larger hospitals typically have pursued hybrid models but favor the use of clearinghouses and internally managed EDI where possible. Smaller hospitals typically rely more heavily on direct data entry, clearinghouses, and/or billing vendors to manage their EDI operations.

A subset of hospitals have reached a level of maturity with Version 4010/4010A transactions and believe that many of the benefits that would be attained by converting to Version 5010 have been mostly achieved. In other words, some hospitals have already taken extensive advantage of EDI, and of the auto adjudication opportunities afforded by Version 4010/4010A, so there may be only incremental benefits for that group, through adoption of Version 5010. These hospitals typically have implemented the full set of transactions (including the eligibility and claim status transactions). Based on the Gartner research, hospitals falling into this category include the 521 hospitals with 400+ beds as well as 20 percent of the mid-sized hospitals with 100–400+ beds and 10 percent of the hospitals with less than 100 beds. These hospitals have consistently deployed an internally managed EDI system and/or a hybrid solution and have invested in substantial development efforts to create workarounds to any problem segments within Version 4010/4010A that were particularly important to their organization. For this subset, the transition to Version 5010 may be more streamlined than for the smaller or less advanced entities because there would be fewer new system and business changes, and more expertise available to resolve implementation issues. However, the benefits would also be less pronounced because those hospitals that have implemented the full suite of transactions with the majority of their partners have already realized the benefits associated with moving from paper, phone or fax transactions to electronic transactions.

Some hospitals (mid-sized and small) have not yet taken full advantage of technical solutions to maximize the use or benefits of the HIPAA standards, and continue to depend on a variety of manual efforts to conduct the various business functions. The transition to Version 5010 would provide significant benefits with respect to a reduction in these manual procedures, resulting in decreased costs and increased efficiencies.

We anticipate the total cost for all hospitals to implement Version 5010 would be within a range of $932 million to $1,864 million. This estimated cost was calculated by applying a 20 percent (minimum) and 40 percent (maximum) factor to the estimated cost of implementing Version 4010/4010A. We provided the cost estimates for Version 4010/4010A for each industry segment in the assumptions section above. While the average costs by hospital would vary based on size and complexity of the hospital system, they would fall within the 20–40 percent range compared to the investments made for implementing Version 4010/4010A. Smaller hospitals typically rely on a billing vendor and/or a clearinghouse for a large majority of their electronic claims exchanges. We assume that these hospitals implemented the 837 transactions only. We assume these hospitals are subject to vendor release schedules and would be dependent on these partners to upgrade their current transactions to the Version 5010 standards. Furthermore, these

smaller hospitals may have to absorb some costs for testing, as testing would represent a significant portion of the overall costs for implementation. Nonetheless, we assume that these costs would be lower for this group than for the larger entities. We assume that many of these hospitals have regulatory compliance clauses in their vendor contracts, which would result in many costs largely being absorbed by their vendors. Our assumptions are based on industry interviews which indicate that small organizations will rely on their vendors for most of the heavy lifting for testing. We believe the impact on the individual entity will be minimal, comparatively. However, we welcome comments and data from the industry and other stakeholders on this matter.

Hospitals would enjoy savings and benefits in the same three categories we identified earlier in the assumptions section of this analysis. Savings due to better standards are estimated to be a minimum of $403 million. Cost savings, due to an increase in use of the electronic claims transactions (837 and 835) are estimated to be a minimum of $67 million. (This figure is derived by multiplying the number of claims times the savings of $.55 per claim (from the AHIP report).) The operational savings for use of the auxiliary transactions (270/271, 276/277, 278) are projected to be a minimum of $1,313 million. (This figure is calculated by taking the number of calls that would be avoided, times the time each of those calls would take times the cost per call.) The benefits related to increased use of the auxiliary transactions would be realized in a reduction in the amount of time that manual intervention would be needed to address the same ''issues'' that can be handled by a transaction. In other words, use of electronic eligibility transactions would save a provider's employee 10 minutes of time per avoided manual intervention or phone call to verify eligibility.

We specifically solicit industry comments on the assumptions made here relative to the costs and benefits for hospitals for the implementation of Version 5010. Table 9b below shows the costs and benefits for all hospitals.

TABLE 9—VERSION 5010 COST BENEFIT SUMMARY FOR HOSPITALS

[In millions]

	Minimum	Maximum	
Costs:			
System Implementation	$792	$1,584	
Transition	140	280	
Total costs	932	1,864	
Benefits:			Formula:
Operational Savings—better standards.	403	1,096	Number of estimated transactions (835/837) requiring a phone call × number of minutes per call × $ average cost per minute.
Cost Savings—increase in electronic claims transactions.	66	219	Number of transactions converted from paper to EDI × estimated cost savings per transaction ($.55).
Operational Savings—increase in use of auxiliary transactions.	1,314	3,414	Number of estimated transactions (270/271, 276/277, 278) requiring a phone call × number of minutes per call x $ average cost per minute.
Total benefits	1,783	4,729	
Net Benefits	851	2,865	

b. Physicians and Other Providers

Physicians have also pursued a variety of implementation models for the HIPAA transactions. They are largely dependent on the requirements of their trading partners (the health plans with whom they conduct transactions) and the services of their vendors and clearinghouses, who provide a range of support and technology, to process the transactions. A full range of implementation methods were considered in this analysis. Larger physician practices have pursued direct transmission with health plans, but many mid-sized practices and small physician practices are dependent on the use of clearinghouses and rely on billing vendors to manage their EDI operations.

For purposes of this cost benefit analysis, Gartner divided physicians practices into four size-based categories, as shown in table 10 below:

TABLE 10—PHYSICIAN BREAKDOWN BY PRACTICE SIZE

Practice size	Number of practices
100+ Physicians	393
50–100 Physicians	590
3–49 Physicians	38,961
1–2 Physicians	194,278
Total	234,222

Source: AMA.

Within these four types of practices, a distinction can be drawn between the groups with more than 50 physicians (large practices) and those that are less than 50 physicians (small practices).

For the large physician practices, as in large hospitals, there are greater levels of acceptance as well as more diversified implementations of the Version 4010/4010A standards. Therefore, the bulk of the costs associated with the implementation of Version 5010 for large practices would be in the category of testing, which we estimate at 60 percent of costs, as explained in the general assumptions section earlier in this document.

The majority of the small physician practices currently utilize vendor supplied practice management software, billing vendors, and/or clearinghouses to handle their HIPAA EDI transactions. For small providers that are PC-based or have client-server systems that rely on vendor-supplied software, we do not believe the provider would bear any immediate costs for the software upgrades. Based on Gartner's interviews and our own experience with the industry, most software maintenance contracts offer free upgrades to accommodate regulatory changes, and we believe that most contracts have clauses that require vendors to be compliant with mandatory standards. However, as with each provider category in which we identified dependence on vendors, there are still testing costs that must be addressed. The impact on those providers that have such contracts would be postponed

until the contract is renewed, and would be mitigated by market factors.

We anticipate that the total conversion cost for physicians would be in the range of $435 million and $870 million. (This was calculated by taking the base of $2,175 million (for implementing Version 4010/4010A), and multiplying that number by version 5010 implementation factor of 20 percent (minimum) and 40 percent (maximum)).

As with hospitals, physicians are positioned to receive the same benefits of using Version 5010, including the previously mentioned savings, through reduced phone calls and reduced manual intervention. Physicians would experience savings and benefits in the three categories as follows: Savings due to better standards is estimated to be $1,613 million. Cost savings, due to an increase in use of the electronic claims transactions (837 and 835) is estimated to be $269 million. (This figure is derived by multiplying the number of claims times the savings of $.55 per claim, as noted in the AHIP study.) The operational savings for use of the auxiliary transactions (270/271, 276/277, 278) is projected to be $5,250 million. (The narrative for these calculations has been provided elsewhere, and the formulas appear in the cost benefit table for hospitals.) Again, we invite public comment on these figures and assumptions, particularly on the assumption that there would be no new hardware costs for implementing Version 5010, since the interviews did not yield information on providers who do not currently have electronic capability. Table 11 below summarizes the cost-benefits for physicians:

TABLE 11—VERSION 5010 COST BENEFIT SUMMARY FOR PHYSICIANS—IN MILLIONS

	Minimum	Maximum
Costs:		
System Implementation	$370	$740
Transition	65	131
Total Costs	435	870
Benefits:		
Operational Savings—better standards	1,612	4,378
Cost Savings—increase in electronic claims transactions	270	874
Operational Savings—increase in use of auxiliary transactions	5,251	13,562
Total Benefits	7,133	18,814
Net Benefits	6,698	17,944

c. Dentists

There are an estimated 175,000 dentists currently covered under HIPAA. However, the dental community has not yet widely adopted the HIPAA standards, in large part because the standards did not meet their practical business needs, particularly for claims and remittance advice. The improvements in Version 5010 would increase the potential value of the HIPAA standards for dentists, and should increase utilization. Currently, the typical dental practice relies on vendor solutions and clearinghouses to handle their Version 4010/4010A HIPAA transactions, and, therefore, the costs for implementing Version 5010 would largely fall on vendors as a cost of doing business. The majority of the dental costs would stem from testing and other related services not covered by any pre-negotiated upgrades with their vendors. Implementation costs for Version 5010 are anticipated to be in the range of $299 million (20 percent) to $598 million (40 percent) based on using the same implementation factor of the Version 4010/4010A implementation costs of $1,493 million.

The benefits derived from implementing Version 5010 for dentists would be the same as those for the other provider segments, as described in the assumptions section of this analysis. For example, based on improvements in Version 5010, we anticipate that for dental practices, there would be an increase in the adoption rate of 2 to 5 percent in the 837 transactions, and 5 to 10 percent in 835 transactions, over a ten-year period.

Increased utilization of the standards would occur because of improvements that specifically affect dental practices. For example, increased utilization of the 837 would occur because the standard now accommodates certain dental terminology to differentiate dental services from medical services. Version 4010/4010A does not allow for reporting diagnoses codes that are required for some specialty claims such as oral and maxillofacial surgery. This has resulted in challenges for this segment of the industry because many of these services are billed using the professional claim, but the professional claim does not have a way to provide tooth numbers or other tooth-related information. These claims often had to be submitted on paper. The ability to report those codes in Version 5010, with the tooth numbers, would provide a standard means for these claims to be submitted electronically. The 835 would be more widely adopted for its ability to post receivables automatically.

In general, we believe dentists would achieve these benefits from operational savings, which would result in:

- Reduced time to determine eligibility
- Reduced manual effort to prepare claims
- Reduced burden to complete account posting
- Greater visibility into claims status

We also expect that dental practices would derive similar benefits as physicians, in the way of savings through reduced phone calls for claims transactions as well as for auxiliary transactions (270/271 and 276/277). For dentists that have not yet implemented 835/837, there would be savings through increased use of EDI. Dentists would experience savings and benefits in the three categories as follows: Minimum savings due to better standards is estimated to be $274 million; minimum cost savings due to an increase in use of the electronic claims transactions (837 and 835) are estimated to be $45 million. (Again, this figure is derived by multiplying the number of claims times the savings of $.55 per claim, as noted in the AHIP study.) The operational savings for use of the auxiliary transactions (270/271, 276/277, and 278) is projected to be a minimum of $889 million. (The narrative for these calculations has been

provided in the assumptions section.) Table 12 below shows the cost benefit summary for the dental industry.

TABLE 12—VERSION 5010 COST BENEFIT SUMMARY FOR DENTISTS—IN MILLIONS

	Minimum	Maximum
Costs:		
System Implementation	$254	$508
Transition	45	90
Total Costs	299	598
Benefits:		
Operational Savings—better standards	274	699
Cost Savings—increase in electronic claims transactions	45	56
Operational Savings—increase in use of auxiliary transactions	889	2,173
Total Benefits	1,208	2,928
Net Benefits	909	2,330

d. Pharmacies

Pharmacies are currently using Version 4010/4010A of the 835 and 837 transactions in their current business practices, most often for the remittance advice (835) and pharmacy supplies and services (837). Pharmacies would transition to the use of Version 5010 when the final rule becomes effective, in particular for the 835 transaction. For retail pharmacy claims, pharmacies primarily use Version 5.1. Since we are proposing to replace Version 5.1 with Version D.0 in this regulation, and many of the system changes, costs and benefits for implementing both Version 5010 and Version D.0 would result from related efforts, we have combined the impact analysis for Version 5010 and Version D.0. That analysis is detailed later in Section 3 of this analysis.

e. Health Plans

According to estimates provided by Gartner, there are nearly 4,000 health plans in the United States. For the purposes of this analysis, we divided plans into four categories based on their size: National and Super Regional Private Plans; Large Private Plans; Mid-Sized Private Plans, and Small Private Plans, as shown in table 13 below.

TABLE 13—HEALTH PLAN BREAKDOWN

Plan size	Number of plans
National and Super Regional	12
Large	75
Mid-sized	325
Small	3,537
Total	3,949

Within these four types of private plans (as described above), there are two distinct scenarios that emerged: Small/Midsized Plans and Large/National/Super-Regional Plans.

The large plans could be characterized as having implemented the full set of 4010/4010A transactions but often did not have trading partners for certain auxiliary transactions. They have already developed workarounds for many of the problems that were identified as being solved in Version 5010. Furthermore, their maturity in working with the Version 4010/4010A transaction set was at a point where they had extracted most of the value from the standards in place.

Small plans resembled the larger plans in that they had implemented the full set of transactions. However, the smaller plans had not developed as many workarounds for Version 4010/4010A limitations as their larger peers. As a result, Version 5010 may serve to provide this segment more benefit on average than their larger peers. In order to calculate health plan implementation costs, we calculated the costs within a factor of 20 to 40 percent of the costs for implementing Version 4010/4010A. Overall, private health plans recognize the importance of continuing to maintain and upgrade the national standards and perceive there to be qualitative benefits that warrant considerations beyond just the quantifiable net benefit from the change.

The benefit for all private plans falls between $5,780 and $15,114 million. Private plans would experience savings and benefits in the three categories as follows: savings due to better standards is estimated to be in a range of $1,283 million to $3,430 million; cost savings, due to an increase in use of the electronic claims transactions (837 and 835) is estimated to be in a range of $111 million and $278 million. (This time, the estimate is derived by multiplying the total number of all claims (physician, hospital, and dental) times the savings of $.18 per claim for plans, as noted in the AHIP study.); the operational savings for use of the auxiliary transactions (270/271, 276/277, and 278) is projected to be in a range of $4,386 million to $11,406 million. (The narrative for these calculations has been provided earlier.) Table 14 depicts total plan cost benefits summary.

TABLE 14—VERSION 5010 COST BENEFIT SUMMARY FOR PRIVATE HEALTH PLANS—IN MILLIONS

	Minimum	Maximum
Costs:		
System Implementation	$3,064	$6,128
Transition	541	1,081
Total Costs	3,604	7,209
Benefits:		
Operational Savings—better standards	1,283	3,430

TABLE 14—VERSION 5010 COST BENEFIT SUMMARY FOR PRIVATE HEALTH PLANS—IN MILLIONS—Continued

	Minimum	Maximum
Cost Savings—increase in electronic claims transactions	111	276
Operational Savings—increase in use of auxiliary transactions	4,386	11,406
Total Benefits	5,780	15,112
Net Benefits	2,175	7,903

Government Plans

To prepare the cost benefit analysis for government plans, we obtained input from Medicare and from several subject matter experts from Medicaid plans across the country. Other government entities, like the Veteran's Health Administration, were assumed to have similar cost/benefit structure as the Large Private plans and were estimated as such. One of the key findings from the interviews was that even in the case of government plans that have implemented the full set of transactions, there is still a very limited exchange of the auxiliary transactions at this time.

Government systems costs are expected to occur across a number of Federal and state agencies and include transition costs. For Medicare, since its cost structure is different from private plans, total Medicare costs include those that would be expended by the MACs, DME MACs, carriers, intermediaries and other contractors. The costs are high, but the net benefit to Medicare relative to the private plans is slightly more positive. Overall, costs for government plans were similar in nature to private plans, and included analysis, translator/software customization, testing, and training. The cost to government systems in transitioning to Version 5010 is estimated to be within a range of $252 million to $481 million over 10 years. This figure was derived by applying a 20 percent and 40 percent factor onto the cost to implement Version 4010/4010A, which was $1,203 million. The examples in this impact analysis are only illustrative in nature and are based on limited analysis. They are presented to illustrate the potential administrative costs to the Federal government.

Derived benefits accrued for implementing Version 5010 to government plans would be similar to those of private plans. Savings would be acquired from reduced phone calls because current ambiguity in the transactions (such as situational versus required information for some of the key data elements) would be reduced. As with all other affected entities, as more uptake of 835/837 messages occur with trading partners, there would be cost savings through lower transaction costs. The same estimates for increased adoption of the 837 transactions of between 2 and 5 percent and between 5 and 10 percent for the 835 transactions would apply to government plans, and we project similar increases in the use of the auxiliary transactions. Since we projected an increase in the market for the auxiliary transactions within the physician community as new uptake occurs with the trading partners (for example, health plans), the government plans would benefit from cost savings as well, as follows: Minimum savings due to better standards are estimated to be $279 million. Minimum cost savings, due to an increase in use of the electronic claims transactions (837 and 835) are estimated to be $24 million. (Again, this figure is derived by multiplying the number of claims times the savings of $.18 per claim, as noted in the AHIP study.) The minimum operational savings for use of the auxiliary transactions (270/271, 276/277, 278) is projected to be $953 million. (The narrative for these calculations has been provided elsewhere.) Table 15 shows the cost benefit summary for government plans.

TABLE 15—VERSION 5010 COST BENEFIT SUMMARY FOR GOVERNMENT HEALTH PLANS—IN MILLIONS

	Minimum	Maximum
Costs:		
System Implementation	$214	$409
Transition	38	72
Total Costs	252	481
Benefits:		
Operational Savings—better standards	279	746
Cost Savings—increase in electronic claims transactions	24	60
Operational Savings—increase in use of auxiliary transactions	953	2,480
Total Benefits	1,256	3,286
Net Benefits	1,004	2,805

f. Clearinghouses and Vendors

Gartner estimates that there are 162 clearinghouses, which includes claims-related transaction vendors. This segment of the HIPAA universe provides a critical service in today's environment. For the purposes of this study, however, any related costs expected to be incurred by these vendors was considered to be a ''cost of doing business'' and were not included in the overall Cost/Benefit impact. Costs were, however, collected from the clearinghouses/vendors and analyzed as best as could be with the information available.

While many providers who use vendor-supplied software may be able to defer the costs of software upgrades, the vendor industry may have to bear, at least initially, the costs of such upgrades. Vendors have not provided data on their costs, and this regulation does not address the costs on the vendor industry, but welcomes input as to the estimated costs and benefits from this industry, for inclusion in the final rule.

For though vendors are not covered entities under HIPAA, their role is significant with respect to the services they provide to health plans and to covered health care provider clients.

We estimate the range of clearinghouse costs to be between $37 million and $45 million for the Version 5010 upgrade over the 3-year implementation period—two years for implementation and a third year for transition. Estimates were determined in the same fashion as the providers and plans. Clearinghouses were estimated to have total Version 4010/4010A costs of approximately $125 million.

We do not estimate that there would be a positive payback related to the Version 5010 upgrade for clearinghouses or vendors, however, there are some discrete benefits that would be realized through this transition including:

- Higher transaction volumes
- Lower service and operational costs (reduced phone calls)
- Operational efficiencies (Lower percent as measured against total costs)
- Increased market size

Because these benefits are predicated on several dependencies and market circumstances beyond our ability to predict with complete accuracy, neither HHS nor Gartner attempted to quantify those in dollar figures. Table 16 below summarizes the clearinghouse costs.

TABLE 16—VERSION 5010 COST BENEFIT SUMMARY FOR CLEARINGHOUSES IN MILLIONS

Costs	Maximum	Minimum
System Implementation	$33	$41
Transition	3	4
Total Costs	37	45

Qualitative Benefits

With few exceptions, sources expressed their belief that the advancement of the HIPAA standards was the right thing to do across the industry. Some participants acknowledged that the advancement to Version 5010 would not benefit their organization directly, but they were still in support of the modifications to the standards.

There were a number of benefits that were articulated but not quantified by the participating subject matter and industry experts that may warrant further discussion with the industry. Among the qualitative benefits that were consistently mentioned by interviewees were the following:

- Improved accuracy resulting from simplified messaging.
- A new field specifically to capture certain hospital acquired condition indicators that are so critical to the industry.
- A new field to capture ''Present on Admission'' indicators as directed by the Deficit Reduction Act.
- Resultant quality through greater reliability of clean message exchange.
- Collaborative benefits stemming from the ability to share more information.

It is also important to note that Version 5010 is considered a key dependency to move towards adopting the ICD–10 CM code set for HIPAA transactions. While there is disagreement in the industry about the benefits of adopting ICD–10 in the next few years, such a transition is viewed as positive over the long-term, and is acknowledged as an option that is not available today. In summary, sources agree that all of the qualitative benefits lead to the delivery of an improved quality of care and allow the providers and plans to focus more of their time on patients and less of their time on administration.

3. Version D.0 (and Version 5010 for Pharmacies)

The objective of this portion of the regulatory impact analysis is to summarize the cost and benefits of implementing Version D.0.

Affected Entities

Almost all pharmacies, health care providers, and plans/PBMs already use Version 5.1, as it is the claim format most widely adopted by providers who submit retail pharmacy claims, and health plans that process retail pharmacy claims. These entities currently use the Version 5.1 standard to transmit retail pharmacy claim information between provider and plans/PBMs, and between pharmacies and plans/PBMs. This is accomplished in one of two ways, either through interactive on-line transmission or transmission through batch mode.

Retail pharmacies use Version 5.1 to submit claims to health plans/PBMs when they dispense a prescription medication to a patient who has prescription drug benefits through his/her health insurance coverage. The National Association of Chain Drug Stores (NACDS) estimates that there are more than 38,000 retail pharmacies owned and operated by both national and regional pharmacy chains that process more than 2.3 billion prescriptions annually. Independent community pharmacies, according to the National Community Pharmacist Association (NCPA) represent an additional 18,000 independent retail community pharmacies across the United States, and process 1.4 billion prescriptions annually.

There are approximately 3,950 health plans according to the America's Health Insurance Plans (AHIP) and Gartner research. With regard to PBMs, there are four national pharmacy benefit management companies that process about 75 percent of the more than 3 billion prescriptions dispensed annually in the United States. The remainder are specialized PBMs.

Some health care providers who dispense medications directly to their patients, known as dispensing physicians, may use the Version 5.1 to submit these prescription drug claims on behalf of their patients to the PBMs and/or plans, depending on the patient's health insurance coverage. However, we do not estimate this practice to be widespread and therefore, do not account for it in this impact analysis. We invite comment regarding the number of pharmacy benefit management companies and their respective market share.

Costs

a. Chain Pharmacies

The retail pharmacy industry would be the most impacted by the transition from Version 5.1. to Version D.0. According to the NACDS, there are nearly 200 chain pharmacy companies in the United States. The programming changes to incorporate the new fields that constitute the Version D.0 are performed at systems located at the corporate level, and then these system updates are pushed out to the individual pharmacies within the pharmacy chain. One large national pharmacy chain has estimated that it spent approximately $10 million when it converted to Version 5.1. In comparison, it anticipates that corporate-wide costs for the conversion to Version D.0, including programming, system testing and personnel training, would be around $2 million. Another large national pharmacy chain estimates its migration costs from Version 5.1 to Version D.0 at $1.5 million. Chain pharmacy cost estimates for programming these systems, testing to ensure that systems work with Version D.0, and training of personnel are dependent on the size of the pharmacy chain, its respective proprietary systems, and number of employees that would require training. Overall, industry estimates for conversion to Version D.0 range from $100,000 for a small pharmacy chain to $1 million for

large national pharmacy chains. We assume that these costs would be incurred in the first year of the implementation of Version D.0, in 2010.

We assume that there are 20 large national pharmacy chains and the remaining 180 chains are small chains. Therefore, we estimate costs for the migration from Version 5.1 to Version D.0 to be $20 million for large national pharmacy chains, and $18 million for the remaining 180 small chains, for a total of $38 million. We estimate that these costs would be incurred during the first two years of implementation.

TABLE 17—CHAIN PHARMACY COSTS FOR CONVERSION TO VERSION D.0

Category	Cost
Large pharmacy chains (20 × $1,000,000)	$20,000,000
Small pharmacy chains (180 × $100,000)	18,000,000

b. Independent Pharmacies

Independent pharmacies would also incur costs, the majority of which would result from upgrading their software systems to Version D.0. These costs are harder to estimate. Independent pharmacies use software dispensing packages purchased from pharmacy dispensing software system vendors, and usually pay a monthly maintenance fee and a per-claim cost of anywhere from 4 cents to 10 cents per claim. Maintenance fees are negotiated between the software vendor and the pharmacies, and may take the form of a flat fee, or a fee based on a sliding scale. These maintenance fees would likely increase slightly, as vendors pass along their cost of the upgrade to the pharmacy. We assume this would take place not during the course of an existing contract, but when the pharmacy's contract with the vendor comes up for renewal, likely within two years, in this case 2010 and 2011, the first two years of Version D.0 implementation. Based on industry feedback, we estimate that the average monthly maintenance contract between a pharmacy and a vendor amounts to a range of $400 to $800 per month per pharmacy, with the average industry estimate being about $500. We estimate a range of between .50 and 1 percent maintenance fee increase attributable to the conversion to Version D.0, or an additional $2.50 to $5.00 per month per pharmacy, or $540,000 to $1,080,000 based on 18,000 independent pharmacies ($500 × 0 .50 percent/1 percent × 12 months × 18,000 pharmacies). We solicit industry and stakeholder comment on our cost assumptions.

TABLE 18—INCREASE IN INDEPENDENT PHARMACY MONTHLY MAINTENANCE FEES FOR CONVERSION TO VERSION D.0

	Percentage of increase to maintenance fees	
Category	.50%	1%
Number of Independent Pharmacies	18,000	18,000
Average monthly maintenance fee	$500	$500
Average annual maintenance fee increase	$540,000	$1,080,000

With respect to costs for implementing Version 5010, we use the same pharmacy categories of chains and independents. As stated above, the retail pharmacy industry would be impacted by the transition from Version 4010/4010A to Version 5010 for billing supplies and services, and receiving the remittance advice (835). Similar to the programming changes to accommodate D.0, the upgrade to Version 5010 would be performed at the corporate level, and the system updates would be pushed out to the individual pharmacies within the pharmacy chain. Estimates from the large national pharmacy chains regarding costs for implementation of Versions 5010 and 5.1 are outlined above. These same entities stated that they anticipate corporate-wide costs for the conversion to Version 5010, including programming, system testing and personnel training, would be around 20 percent of the Version 4010/4010A costs. This is consistent with the overall industry estimate that implementation of Version 5010 would represent approximately 20 to 40 percent of the cost of implementing Version 4010/4010A. As with Version D.0, chain pharmacy cost estimates for programming, testing, and training are dependent on the size of the pharmacy chain, their respective proprietary systems, and the number of employees that would require training. We assume that these costs would be incurred in the first 2 years of the implementation of Version 5010, as we do with the other HIPAA standards and other industry segments.

Independent pharmacies would also incur costs, the majority of which would result from upgrading software systems to Version 5010 and Version D.0, as has been discussed. Independent pharmacies use software dispensing packages, and usually pay a monthly maintenance fee and a per-claim cost. We assume that these types of costs for implementing Version 5010 would be incorporated into the costs for implementing Version D.0, and therefore do not add additional costs. Thus, using the same estimates for the number of chain and independent pharmacies, and applying a rate of 20 percent to Version 4010/4010A implementation costs, we estimate costs specific to the migration from Version 4010/4010A to Version 5010 to be a range of $58 million to $114 for system implementation and $10 million to $20 million for transition costs, for a total range of $67 million to $134 million. We assume that these costs would implicitly include testing, as this activity would be executed jointly for Version D.0 and Version 5010. We invite the industry to comment on our assumptions and projected cost estimates, and to provide current data to support alternative theories or view points, as the comparison between Version 4010/4010A costs and Version 5010 implementation costs could be overstated.

We described the benefits for all providers, including pharmacy providers, in the assumptions section of this analysis (for example, better standards and decreased manual effort). We identified the largest benefits for pharmacies in the content requirements in the 835 standard (required fields versus situational or optional fields, and improvements in the specificity of the business rules which will minimize multiple interpretations of the guides). These enhancements would help to reduce manual interventions needed to resolve transaction issues. For example, Version 4010/4010A does not provide instructions for reconciling payments. The new Front Matter section in Version 5010 explicitly details how this information is to be reported in the

summary section of the remittance advice. Thus, benefits and savings would accrue through better standards. For this savings calculation, we use the same formula as for other provider cost savings—multiplying the number of claims that would not require manual intervention, times the cost per call and the number of minutes estimated for each call. Savings due to better standards (837 and 835) are estimated to be in the range of $20 million to $27 million.

c. Health Plans and PBMs

Health plans should see minimal changes in their operations and workflows between Version 5.1 and Version D.0. Version D.0 does not require any substantial or additional data reporting to enhance the eligibility or subrogation/secondary plan aspects of the transaction. Most of that work would be performed by the pharmacy benefit managers (PBMs) that service the plans. Plans would likely continue to provide data to the PBMs weekly via flat file transmission. However, PBMs would have to reprogram their systems to be able to process claims in Version D.0. As with the large pharmacy chains, we estimate the cost for large PBMs to migrate to Version D.0 to be approximately $1 million to $1.5 million per large national PBMs, and approximately $100,000 for specialty PBMs. Due to mergers and acquisitions over the past 4 years, the number of PBMs has dropped from approximately 100 to about 40 total PBMs in the U.S. Of those, we estimate that four are considered large PBMs and would therefore incur approximately $4 million to $6 million in conversion costs to Version D.0, and the remainder would incur $100,000 or $3,600,000 in the aggregate, for a total cost ranging between $8.6 and $10.6 million. We do not estimate any additional costs to health plans for implementing Version 5010 for pharmacies, as all efforts are included in the overall budget towards compliance. We solicit industry comment on these cost assumptions, and additional information regarding how PBM costs affect health plans, and how these costs are passed on to the plans. We also invite comment as to how the change to Version D.0 would affect core systems, and what the costs might be to health plans, particularly large plans with broad operations.

TABLE 19—PBM COSTS OF CONVERSION TO VERSION D.0

Category	Cost
Large PBMs (4 × $1,000,000/ $1,500,000).	$4,000,000/ $6,000,000
Specialty PBMs (36 × $100,000).	$3,600,000

d. Vendors

Software vendors have commitments to their software clients to maintain compliance with the latest adopted e-prescribing standards. They must incorporate these standards into their software systems, otherwise they would not be able to sell their products competitively in the marketplace. These systems cannot properly function using outdated standards and/or missing key functionalities which the industry has identified as essential to their business operations. We expect that upgrades to these standards are anticipated by vendors, and the cost of programming and/or updating the software is incorporated into the vendor's routine cost of doing business. We further assume they would pass along costs to customers through increases in the cost of licensing and/or monthly maintenance fees, which we previously discussed and estimated to be about 0.50 to 1 percent based on industry interviews. We solicit industry and stakeholder comment on the assumption that vendor costs will be passed on to the customer over time, and solicit feedback on actual costs for vendor software upgrades and impact on covered entities, including the conversion of historical data.

Benefits

a. Pharmacies

Pharmacies need Version D.0 to process Medicare Part D claims. Currently, there are many workarounds in pharmacy systems due to the shortcomings of Version 5.1 in processing ''coordination of benefits'' claims. Pharmacies would benefit from the use of the NCPDP D.0 standard because it provides better guidance than Version 5.1 in Medicare Part D coordination of benefits situations, and now identifies ''patient responsibility'' and ''benefit stage'' to help identify coverage gaps on secondary claims. By processing the claim correctly the first time—sending the right fields, with the right details, and additional fields with detailed pricing segments—the result could be that pharmacies are paid correctly, and patients pay correct co-pays, and there could be fewer pharmacy audits and recoupments.

A recoupment is a request for refund when a pharmacy is erroneously overpaid by a plan. A common reason for a recoupment is that the plan was not aware of a patient's other health insurance coverage, information that can be provided through use of the Version D.0 standard. Currently, there are issues with Version 5.1's misinterpretation of ''coordination of benefits.'' There are extensive customer service issues with many of these claims due to the charging of incorrect co-pays, as the correct values do not exist in Version 5.1. Version D.0 redefines the ''other coverage codes'' and provides claim examples in coordination of benefits situations to eliminate future confusion. Extra information, which would be available in the E1—Eligibility Verification transaction (this transaction resides on the NCPDP Telecom 5.0 standard and provides information on a patient's benefit eligibility at the time of prescription dispensing) would be beneficial to pharmacies as well, but it is the coordination of benefits and more precise pricing fields that would save pharmacies time and money. One industry group estimated that large pharmacy chains could save upwards of $1 million a year due to avoided audits and incorrect payments. For smaller chains, the industry estimates savings would be approximately $100,000 per chain. This does not include the time that pharmacists and pharmacy technician staff spend on these claims trying to process them at the pharmacy level. We assume an annual benefit of $38 million for large and small pharmacy chains in avoided audits and incorrect payments, and a total 10-year benefit of $380 million, and conservatively estimate benefits at 50 percent, or $190 million. We invite industry and stakeholder comments on this assumption.

Table 20 below shows the amount of savings as a result of avoided audits and incorrect payments based on implementation of Version D.0.

[Large and small chain pharmacy avoided audit and incorrect payment savings resulting from Version D.0 (millions)]

Benefit type	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Large Pharmacy chains (20 × $1M)	$20	$20	$20	$20	$20	$20	$20	$20	$20	$20	$200
Small Pharmacy Chains (20 × $1M)	18	18	18	18	18	18	18	18	18	18	180
Total (maximum)	38	38	38	38	38	38	38	38	38	38	380
50% (minimum)	19	19	19	19	19	19	19	19	19	19	190

Based on a study funded by the National Association of Chain Drug Stores (NACDS), ''Pharmacy Activity Cost and Productivity Study'' (*http://www.nacds.org/user-assets/PDF_files/arthur_andersen.PDF*), the average pharmacist spends 1.1 percent of his or her time dealing with third party plan issues. According to NACDS, there are 136,773 pharmacists employed by chain pharmacies, and 94,000 full-time community pharmacists. In 2010, the first year of the migration from Version 5.1 to Version D.0, that number is expected to increase to 244,829, or approximately 7,028 per year based on industry trend information. For these 244,829 full-time pharmacists, 1.1 percent of 2,080 working hours annually equals 22.88 hours per year that a pharmacist spends on third party plan issues, times the study's estimated average pharmacist hourly wage of $60, which equals $1,373 per pharmacist, $1,373 × 244,829 full-time pharmacists equals $336,101,251 in potential productivity savings to be realized by the use of Version D.0 in the first benefit year. However, we recognize that all call backs and inquiries would not be entirely eliminated. Therefore, we conservatively estimate that 25 to 50 percent of the pharmacist's time spent on third party plan questions could be eliminated, for a total first year savings of $84 million to $168 million. Over the next 9 years, we estimate that, based on Department statistics (*http://www.hhs.gov/pharmacy/phpharm/howmany.html*) the number of pharmacists will increase by 1.3 percent per year. We estimate 10-year productivity savings at $1,134 million to $2,268 million. We did not estimate hourly wage increases for the other job types discussed elsewhere in this regulation, and therefore savings calculated for other entities do not include the additional dollar values.

TABLE 21—PHARMACIST PRODUCTIVITY SAVINGS FROM VERSION D.0

Year	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	
No. of Pharmacists	244,829	248,012	251,236	254,502	257,811	261,162	264,557	267,996	271,480	275,010	2,596,595
Incremental Pharmacists		3,183	3,224	3,266	3,309	3,352	3,395	3,439	3,484	3,529	30,181
Pharmacist Hourly Wages	$60.00	$63.18	$66.52	$70.04	$73.75	$76.65	$80.76	$85.04	$89.54	$94.28	
Hours × Wages × Pharmacists	$336,101,251	$358,515,508	$382,375,458	$407,843,319	$435,029,477	$458,013,485	$488,845,770	$521,444,688	$556,175,087	$593,230,486	$4,537,574,528
Total (25%)	$84,025,313	$89,628,877	$95,593,864	$101,960,830	$108,757,369	$114,503,371	$122,211,442	$130,361,172	$139,043,772	$148,307,621	$1,134,393,632
Total (50%)	$168,050,626	$179,257,754	$191,187,729	$203,921,659	$217,514,738	$229,006,742	$244,422,885	$260,722,344	$278,087,544	$296,615,243	$2,268,787,264

According to the same NACDS study, pharmacy staffs spend 0.9 percent of their time dealing with third party plan issues. Although there are usually multiple pharmacy technicians on premises at a given time, for purposes of this analysis we assume that one and one-half pharmacy staff persons per pharmacy are addressing these third party plan issues.

In projecting the growth in the number of pharmacies over the next 9 years, we used data from the NACDS, ''Community Retail Pharmacy Outlets by Type of Store, 1996–2006'' (*http://www.nacds.org/user-seets/pdfs/facts_resources/2006/Retail_Outlets2006.pdf*), which showed that while there were 2 years of negative growth, the average percentage increase in the number of pharmacies was .835 percent per year. We applied this percentage growth factor to our analysis, and calculated benefits based only on the incremental growth in the number of pharmacies, assuming that existing pharmacies would have already accounted for their technician hours. We also assume that the salaries of pharmacy technician staff would rise approximately $.50 cents an hour each year, based on industry data (*http://flahec.org/hlthcarers/pharmtec.htm* and *http://www.nacds.org/wmspage.cfm?parm1=507*) showing that their median hourly earnings rose from $11.73 in 2005, to $12.74 in 2007. Starting our analysis in the year 2010, we project there would be 56,946 pharmacies. We assume that one and one-half full-time pharmacy staff persons per pharmacy would spend 28.08 hours per year on third party plan issues (0.9 percent × 3,140). The hourly wage for one and one-half persons is $21.36 based on a per-technician hourly wage projected at $14.24 (1.5 × $14.24=$21.36) for the year 2010. This 2010 hourly wage is based upon the current average hourly wage of $12.74, increased 0.50 cents per year according to industry trend information. We calculated the 2010 hourly technician wage of $21.36 times the number of hours spent on third party plan issues, 28.08, times the number of pharmacies, 56,946 for a total of $34,155,573 ($21.36 × 28.08 × 56,946). Once again, we recognize that all call backs and inquiries would not be entirely eliminated. Therefore, we conservatively estimate that 25 percent of the pharmacy staff's time spent on third party plan questions could be eliminated, for a total 10 year productivity savings of $98 million to $196 million.

TABLE 22—PHARMACY TECHNICIAN STAFF PRODUCTIVITY SAVINGS FROM VERSION D.0

Year	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	
No. of Pharmacies	56,946	57,421	57,900	58,383	58,870	59,361	59,856	60,355	60,858	61,366	.....
Incremental No. of Pharmacies	.....	475	479	483	487	491	495	499	503	508	.....
Technician Hourly Wage (×1.5 techs.)	$21.36	$21.86	$22.36	$22.86	$23.36	$23.86	$24.36	$24.86	$25.36	$25.86	.....
Hours (28.080) × Wages × No. of Pharmacies ...	$34,155,573	$35,246,664	$36,353,604	$37,476,561	$38,615,706	$39,771,205	$40,943,228	$42,131,942	$43,337,517	$44,560,847	$392,592,847
Total (25%)	$8,538,893	$8,811,666	$9,088,401	$9,369,140	$9,653,926	$9,942,801	$10,235,807	$10,532,986	$10,834,379	$11,140,212	$98,148,212
Total (50%)	$17,077,787	$17,623,332	$18,176,802	$18,738,281	$19,307,853	$19,885,603	$20,471,614	$21,065,971	$21,668,759	$22,280,424	$196,296,424

Health Plans and PBMs

We assume that if pharmacists and technicians realize productivity savings as a result of the use of Version D.0, then conversely, health plans and PBMs would realize commensurate savings though a reduction in pharmacist and technician calls to customer service representatives at health care plans and PBMs.

Using the previous assumptions, we again estimate the annual salary of a typical plan/PBM customer service representative at $40,000, or approximately $19.23 per hour. If pharmacists spend a total of 22.88 hours per year on the phone making third party payer inquiries, we estimate that a customer service representative would spend the same amount of time on the phone answering the pharmacists' third party inquiries. At $19.23 an hour, that would equate to savings of $440 per customer service representative. Additionally, if pharmacy technicians each spend 28.08 hours each year on the phone making third party payer inquiries, this would equate to $540 per customer service representative, for a total savings of $980 per customer service representative. If we apply a conservative benefit assumption of 25 percent, this would equate to productivity savings of $245 per customer service representative.

We have no knowledge of the number of customer service representatives employed by plans and PBMs, and therefore cannot draw any quantitative conclusions from the above analysis. We assume that, even taking a conservative approach by estimating the benefit at 25 percent as we did for the pharmacists and technicians, plans and PBMs would greatly benefit from productivity savings among their customer service representatives in avoided calls from pharmacists and technicians regarding third party payer issues.

We also assume that if pharmacies are realizing savings through avoided audits and returned payments, plans are also receiving a commensurate benefit, but we have no data from industry to support this assumption. We solicit industry and interested stakeholder comments on these benefit assumptions.

With respect to benefits related to implementing Version 5010, we described the benefits for all providers, including pharmacy providers, in the assumptions section of this analysis (better standards and decreased manual effort). We identified the largest benefits for pharmacies in the content requirements in the 835 standard (required fields versus situational or optional fields) and improvements in the specificity of the business rules which will minimize multiple interpretations of the guides. These enhancements will help to reduce manual interventions needed to resolve transaction issues. For example, Version 4010/4010A does not provide instructions for reconciling payments. The new Front Matter section in Version 5010 explicitly details how this information is to be reported in the summary section of the remittance advice. Thus, benefits and savings would accrue through better standards. For this savings calculation, we use the same formula as for other provider cost savings—multiplying the savings from reduced manual intervention by the number of claims and remittance advice transactions that would be affected by the improvements. Savings due to better standards (837 and 835) is estimated to be in the range of $20 million to $27 million.

TABLE 23—COST SAVINGS FOR PHARMACIES DUE TO BETTER STANDARDS FOR VERSION 5010

[In millions]

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Decrease in phone calls	.....	.....	.77	.80	.83	.86	.90	.93	.97	1.01	.....
Time to process call—6 minutes	0	0	$2	$2	$2	$2	$3	$3	$3	$3	$20
Cost per call—$.48/minute	0	0	$3	$3	$3	$3	$3	$4	$4	$4	$27

Summary of Version D.0 and Version 5010 for Pharmacy Costs and Benefits

Costs would be incurred by pharmacy chains, independent pharmacies and PBMs in the migration from Version 5.1 to Version D.0. Benefits resulting from avoided audits and incorrect payments, and pharmacist and pharmacy technician productivity savings would accrue to pharmacy chains and independent pharmacies.

TABLE 24—COST BENEFIT SUMMARY FOR PHARMACIES IN MILLIONS FOR VERSION D.0 AND VERSION 5010

	Minimum	Maximum
Costs (Chains and independents):		
D.0 Pharmacy Chains Systems Implementation	$18	$38
D.0 Independent Pharmacies Maintenance Fees	540	1,080
D.0 PBM Programming	8.6	10.6
5010 System Implementation	58	114
5010 Transition	10	20
Total Costs	95.14	183.6
Benefits:		
D.0 Pharmacist Productivity Savings	1,134	2,268
D.0 Pharmacy Technician Productivity Savings	98	196
D.0 Avoided Audits and Accurate Payments	190	380
5010 Operational Savings—better standards	20	27
Total Benefits	1,442	2,871
Net Benefits	1,346	2,870

3. Version 3.0

A. Introduction

All State Medicaid programs or their business associates that conduct Medicaid pharmacy subrogation transactions for pharmacy claims would be required to use the NCPDP Medicaid Subrogation Standard, Version 3.0 when billing third party payers that may be legally responsible for payment.

Based upon industry analysis and current usage, we have determined that adopting a standard for the subrogation transaction would result in one-time conversion costs for Medicaid State agencies, or their business associates, as well as the third party payers of Medicaid claims. This includes primarily pharmacy benefit managers (PBMs) and claims processors as well as medical health plans that process their claims in house. Some third party payers would incur system upgrade costs directly and others would incur them in the form of a fee paid to a contractor. We project that the accrued savings that would result from the administrative simplification of adopting a HIPAA standard for Medicaid pharmacy subrogation would be ongoing and offset any immediate expenditures.

B. Current Medicaid Claims Processing Environment

Approximately 37 States are currently billing a major portion of their Medicaid pharmacy subrogation claims electronically. At the time of this impact analysis, 33 of the 37 States were using a contingency fee contractor to bill their claims. This means that these States have hired a contractor to seek reimbursement from third parties and the contractor keeps a portion of the recoveries. The other four States were billing electronically without the use of a contractor. The remaining 14 States were billing primarily all of their Medicaid pharmacy subrogation claims on paper.

It is important to note that since some payers currently require the use of their own unique billing format, States and contractors with electronic billing capability have found it necessary to bill a substantial amount of subrogation claims on paper.

In addition, due to the current challenges of having to use various formats to meet the needs of different payers, some States, on occasion, recoup the subrogation monies directly from pharmacy providers, and the providers are responsible for billing the payers. The impact on pharmacy providers for implementing the NCPDP subrogation format is discussed in section D of this proposed rule.

C. Impact Analysis on State Medicaid Programs

The current Version 2.0 for standard Medicaid pharmacy subrogation, with some modifications to accommodate various third party payers, is being widely used. Therefore, some of the costs referenced in this impact analysis have already been absorbed.

The costs for States that currently bill electronically to upgrade their systems to Version 3.0 for Medicaid subrogation transactions, and to transition from paper Medicaid subrogation claims to electronic Version 3.0, would be outweighed by the benefits accrued to States. The following sections provide details to support this conclusion. We invite public comments on this conclusion.

1. Impact on States That Use a Contingency Fee Contractor

For the 33 States that contract out their Medicaid pharmacy subrogation billing processes, there would be no direct costs. Contingency fee contractors generally keep a percentage, from 6 percent to 15 percent, of the monies they recover from third parties. It is expected that these contractors would absorb the upfront costs. If the standard is adopted, we project that reimbursement to States would increase proportionally to a projected increase in volume of electronic claims, and as a result, the contractors would recover their cost on the back-end, as they would be recouping additional contingency fees based on the volumes.

Our estimates are based on the assumption that virtually all paper subrogation claims would be converted to electronic transactions because currently, some States only conduct subrogation on paper. With the adoption of Version 3.0 as a HIPAA standard, all States (or their contractors) will be required to utilize Version 3.0 when transmitting Medicaid subrogation claims to plans or payers.

2. Impact on States Converting From Paper

The total costs and benefits to the Federal government and State Medicaid programs are arrayed in Tables 24a and 24b at the end of this section.

a. Cost of Development

The typical steps to be taken in the implementation of the Version 3.0 include:

- Completing an analysis to identify gaps and weaknesses in existing process.
- Participating in internal meetings for project management and control.
- Completing documentation requirements necessary for project management.
- Providing translator training to development staff.
- Completing new translator maps for both the outgoing NCPDP claim and the returning NCPDP response files.
- Completing legacy system changes to accommodate the NCPDP transactions.
- Completing acceptance testing.

Since States have already made the necessary investments in developing electronic transaction capabilities to meet HIPAA mandates and they anticipate upgrading their systems in order to adopt the NCPDP D.0 standard for processing claims, we expect that additional infrastructure costs would be relatively small. Costs would be significantly reduced because the Medicaid subrogation standard Version 3.0 utilizes the data elements in, and operates in conjunction with, the version D.0 claim standard.

We captured data from the State of Illinois, which recently adopted Version 2.0 for pharmacy subrogation as a stand-alone systems upgrade. The cost for development was estimated at $220,000 for staff and mainframe systems. This figure does not include costs on the Local Area Network (LAN) where the translator development and testing occurred, or connectivity setup costs performed by another agency. Illinois is the only state that has recently converted to Version 2.0 and was able to provide cost data. Alabama is in the process of converting to Version 2.0, but its implementation is being done in conjunction with other system upgrades, and the costs specific to Medicaid subrogation could not be isolated.

Since we believe it is unlikely that a State would choose to use the Medicaid pharmacy subrogation standard as a stand-alone upgrade, but instead would implement it in conjunction with Version D.0, we project the cost to be lower. Therefore, we would expect the cost of adopting the Medicaid subrogation standard in conjunction with adopting the Version D.0 to range from $50,000 to $150,000 per State. The State would be responsible for 10 percent of the $50,000 to $150,000 per State, and the Federal government would reimburse the State 90 percent of the design, development, and installation costs related to changes in their Medicaid Management Information Systems (MMIS).

Of the 14 States that bill paper, we project that seven would incur

development costs in order to conduct their own billing and the other seven would hire a contingency fee contractor to conduct their billing.

However, since we have received a limited amount of data, we solicit comments from States.

b. Costs of Adopting and Implementing Trading Partner Agreements (TPAs) With Third Party Payers

Once a State has a system in place to process pharmacy claims using the Medicaid subrogation standard, the State typically enters into ''Trading Partner Agreements'' with other payers in order to conduct subrogation electronically. This involves—

- Outreach activities.
- Meetings to assure that the strategy developed will accomplish a successful implementation.
- Connectivity for file transfers and to mitigate the values in various fields in outgoing NCPDP claim transactions and the returning NCPDP response transaction.
- Modifications to accommodate the needs in the translator maps and legacy systems.
- Acceptance testing and deployment scheduling.

According to the AHIP, there are four national PBMs that process about 75 percent of all prescriptions dispensed annually, and there are a small handful of specialized PBMs. Based on information provided by States and business associates, we expect that approximately forty (40) third party payers, primarily PBMs and claims processors as well as a few large health plans that process claims in-house, would be affected.

Based on estimates from some at least two States (Illinois and Alabama) that have recently, or are in the process of, billing electronically, the cost to adopt and implement their first trading partner agreements are estimated to range from $14,000 to $20,000. We believe that as States and payers gain experience in negotiating these agreements and the number of these agreements increases, the cost would be significantly reduced. Therefore, we estimate the cost for a State to establish and implement trading partner agreements with payers to range from $5,000 to $15,000 for each trading partner agreement. It is projected that each State would enter into a trading partner agreement with an average of 15 payers. The anticipated costs per State would range from $75,000 to $225,000. Since we believe that one half of the 14 States would hire a contractor, the costs for the other seven States to adopt a trading partner agreement with 15 plans would range from $525,000 to $1.6 million. The State would be responsible for 50 percent of the cost since the Federal government reimburses States 50 percent of their administrative costs, related to the proper and efficient administration of the Medicaid program.

3. Impact on States That Bill Electronically (Without the Use of a Contingency Fee Contractor)

a. Cost of Development

For the four States that are currently conducting pharmacy subrogation transactions electronically, the changes would be minimal and the cost impact would be much less than for the States that currently bill paper to convert to Version 3.0.

b. Costs of Adopting and Implementing Trading Partner Agreements With Third Party Payers

The cost to adopt and implement a trading partner agreement would be the same: $5,000 to $15,000, for these States as it would be for the States that are converting from paper to electronic billing. The only difference is that these States would have already established trading partner agreements with some payers and would be setting up trading partner agreements with additional payers. We would estimate that these four States would each establish trading partner agreements with an additional 12 payers for a total cost ranging from $20,000 to $60,000.

4. Medicaid Savings

We have determined that the accrued savings to States would outweigh the costs based on the fact that after implementation, Medicaid agencies would no longer have to keep track of and use various electronic formats for different payers. This would simplify their billing systems and processes and reduce administrative expenses.

Based on our data, we estimate the total number of paper Medicaid pharmacy subrogation claims to be between 2.5 and 3.4 million annually. We are seeing a trend where States that have historically ''paid and chased'' pharmacy claims are implementing cost avoidance systems. By doing so, States are requiring pharmacy providers to bill third party payers before billing Medicaid, thereby reducing the need for Medicaid subrogation. We expect this trend to continue.

According to a study by Milliman in 2006, and referenced by the American Medical Association (AMA) on their Web site, electronic claims can save an average of $3.73 per clean claim filed. Based on this study, the Medicaid program stands to save an estimated $12.7 million annually once Version 3.0 is fully implemented, beginning in the third year of implementation. For the third and fourth year when Version 3.0 is fully implemented, the administrative savings will be distributed equally between the States and the Federal government. The total savings over the 10 year period is estimated to be $17.6 million. After the fourth year, savings will essentially cease as States transition to routine use of the standard.

Rather than using the assumptions that the AHIP study referenced earlier in this analysis for Version 5010, we use the study referenced by the AMA because it identifies savings for the entity that generates the claim, which, in the case of subrogation, is the Medicaid agency. We believe that this $3.73 savings estimate represents the savings potential of overhead, labor, and other indirect benefits applicable to Medicaid. The AMA report referencing the study can be found at: *http://www.ama-assn.org/ama/pub/category/18185.html.* Select ''Follow the Claim'' to be taken to the report. The study itself can be found at *http://transact.webmd.com/milliman_study.pdf*.

The savings represents both State agencies and the Federal government, as the Federal government would share 50 percent of any administrative savings. We did not receive specific data from Medicaid agencies on subrogation savings, and therefore welcome industry input and data to validate or enhance these assumptions during the public comment period.

In addition to the administrative savings, we anticipate that Medicaid would realize programmatic savings resulting from an increase in claims paid due to increased efficiency in electronic claims processing using Version 3.0. We do not have sufficient data to accurately project the actual savings; therefore, we solicit public comments.

We do not anticipate a significant change in volume in subrogation claims in future years. Even though the trend shows an increase in prescriptions overall, States are becoming more efficient in avoiding payment on the front-end which results in fewer subrogation claims on the backend.

D. Impact on Medicaid Pharmacy Providers

In situations where Medicaid has been unable to successfully bill third parties, due to the current challenges of having to use various formats to meet the needs of different payers, States sometimes recoup the subrogation monies from pharmacy providers and it

is left up to the providers to bill the appropriate third party payers. Use of a standard format should enable States to bill third parties successfully and therefore help to alleviate this administrative burden on providers. We do not estimate this practice to be widespread and therefore do not account for it in this impact analysis.

E. Impact on Third Party Payers (Includes Plan Sponsors, Pharmacy Benefit Managers (PBMs), Prescription Drug Plans (PDPs) and Claims Processors)

Insurers, employers and managed care plans are sometimes referred to as plan sponsors. A majority of plan sponsors use a PBM to manage prescription drug coverage and handle claims processing. Some plan sponsors administer the prescription coverage in-house, but contract with a claims processor just to handle claims adjudication. A few of the larger plan sponsors perform their own claims processing. The total costs and benefits to third party payers are arrayed in Table 25a and Table 25b at the end of this section.

1. Impact on Plan Sponsors That Use a PBM or Claim Processor

As mentioned earlier, there are four PBMs that handle about 75 percent of all prescription orders dispensed annually in the United States, and a handful of specialized PBMs. These PBMs have contracts with hundreds of plan sponsors. We estimate that about 10 PBMs and processors are already accepting the Version 2.0 subrogation standard from States or their contractors.

For the majority of plan sponsors that contract out their claims adjudication to PBMs or claims processors, the costs of implementing Version 3.0 and establishing trading partner agreements would be minimal. The PBMs and claims processors would likely absorb the upfront cost and recover their expenses from their hundreds of plan sponsors on the back-end. This could be done by charging a flat fee or by increasing the amount of the transaction fees that are charged to plans sponsors for processing Medicaid claims. These fees would be offset for plan sponsors since they would no longer be paying higher fees for processing paper claims.

2. Impact on Plan Sponsors That Do Not Use a PBM or Claim Processor

There may be a few large payers, primarily insurers and managed care organizations that administer their own claims adjudication. These payers would have already made the necessary investments in developing electronic capabilities to meet HIPAA mandates. We anticipate that the payers would upgrade their systems in order to adopt the Version D.0 for processing claims from providers. Version 3.0 utilizes a number of the data elements found in Version D.0. Therefore, we expect that additional infrastructure costs would be relatively small.

a. Costs of Development

We estimate the development costs to individual payers that would need to implement Version 3.0 for the Medicaid pharmacy subrogation standard, Version 3.0 to be similar to the cost for State Medicaid programs which would be in the $50,000 to $150,000 range. We estimate that there are about 20 payers that do not contract with a PBM and they would need to upgrade their systems at a total cost of $1 to $3 million. However, since we do not have sufficient data to accurately project actual costs, we solicit comments from third party payers.

b. Costs of Adopting and Implementing Trading Partner Agreements With States

We estimate the plan sponsor's costs of adopting and implementing a trading partner agreement with a State would be similar to the cost estimated for State Medicaid programs, which would range from $5,000 to $15,000 per agreement.

We anticipate that approximately 40 States would utilize a contingency fee contractor, therefore, the process for setting up trading partner agreements with a contractor versus 40 individual States would be streamlined and much less costly. We estimate the cost per plan sponsor for establishing agreements to include all of the States to range from $60,000 to $180,000. However, since we do not have sufficient data, we solicit comments from plan sponsors.

In addition to the administrative costs, we anticipate that the increased efficiency in claims processing would result in payers paying out more for Medicaid subrogation claims that would have otherwise been denied. We do not have sufficient data to estimate the potential costs. We invite public comments on the costs for the increase in Medicaid subrogation adjudicated claims.

3. Savings Impact

Savings from the application of electronically conducting subrogation may vary, but even small savings per claim can have a large impact on administrative costs when dealing with large claim volumes.

According to a survey conducted by AHIP in May 2006, electronic claims are roughly half the cost of paper claims. The average cost of processing a clean electronic claim was 85 cents, nearly half the $1.58 cost of processing a clean paper claim. Pended claims requiring manual or other review cost $2.05 on average per claim to process.

We do not have data for the States to distinguish the proportion of clean claims versus those that require manual review. Using the assumption that 50 percent of claims require manual review, the savings of converting 3.4 million paper claims to electronic transmission would be $3.3 million. Use of the standard would provide a source of ongoing savings for the industry.

We do not anticipate a significant change in volume in subrogation claims in future years. Even though the trend shows an increase in prescriptions overall, States are becoming more efficient in avoiding payment on the front end which results in fewer subrogation claims on the backend. The following tables (Table 25a/b and 26a/b) show the estimated State, Federal and payer costs and benefits for implementing Version 3.0.

TABLE 25a—ESTIMATED STATE AND FEDERAL COSTS IN MILLIONS—FOR YEARS 2010–2019 FOR IMPLEMENTATION OF VERSION 3.0

Cost type	Government plans	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Development	Federal—Minimum	$.158	$.158	0	0	0	0	0	0	0	0	$.316
	Federal—Maximum	.472	.472	0	0	0	0	0	0	0	0	.944
	State—Minimum	.018	.018	0	0	0	0	0	0	0	0	.036
	State—Maximum	.052	.052	0	0	0	0	0	0	0	0	.104
Trading Partner Agreements	Federal—Minimum	.191	.191	0	0	0	0	0	0	0	0	.382
	Federal—Maximum	.580	.580	0	0	0	0	0	0	0	0	1.160
	State—Minimum	.191	.191	0	0	0	0	0	0	0	0	.382
	State—Maximum	.580	.580	0	0	0	0	0	0	0	0	1.160

TABLE 25b—ESTIMATED STATE AND FEDERAL BENEFITS—IN MILLIONS—FOR YEARS 2010–2019 FOR IMPLEMENTATION OF VERSION 3.0

Benefit type	Government plans	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
General Benefit	Federal—Minimum	$1.16	$2.33	$4.7	$4.7	$0	$0	$0	$0	$0	$0	$12.9
	Federal—Maximum	1.59	3.17	6.4	6.4	0	0	0	0	0	0	17.59
	State—Minimum	1.16	2.33	4.7	4.7	0	0	0	0	0	0	12.9
	State—Maximum	1.59	3.17	6.4	6.4	0	0	0	0	0	0	17.59

TABLE 26a—ESTIMATED PAYER COSTS—IN MILLIONS—FOR YEARS 2010–2019—FOR IMPLEMENTATION OF VERSION 3.0

		2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Costs:												
Development	Payer—Minimum	$.500	$.500	$0	$0	$0	$0	$0	$0	$0	$0	$1
	Payer—Maximum	1.5	1.5	0	0	0	0	0	0	0	0	3
Trading Partner Agreements	Payer—Minimum	1.2	1.2	0	0	0	0	0	0	0	0	2.4
	Payer—Maximum	3.6	3.6	0	0	0	0	0	0	0	0	7.2

TABLE 26b—ESTIMATED PAYER BENEFITS—IN MILLIONS—FOR YEARS 2010–2019—FROM IMPLEMENTATION OF VERSION 3.0

General Savings	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Payer—Minimum	$.600	$1.24	$2.475	$2.475	$0	$0	$0	$0	$0	$0	$6.79
Payer—Maximum	.800	1.65	3.3	3.3	0	0	0	0	0	0	9.05

D. Alternatives Considered

We considered a number of alternatives for each of the proposals and eliminated each of them in favor of the recommendations in this proposed rule.

For each of the three sections of this proposed rule, one alternative considered was to make no changes to the status quo. That would mean that the current versions of X12N (Version 4010/4010A) and NCPDP (Version 5.1) would continue to be the adopted standards for HIPAA transactions, and that a standard would not be adopted for Medicaid subrogation transactions. In each case we rejected this alternative because such a decision would not only continue to hamper adoption of EDI for all covered entities, it would potentially preclude the industry from implementing the ICD–10 code set for the HIPAA administrative transactions. We note that Version 4010/4010A cannot accommodate ICD–10 codes, while Version 5010 can. Keeping version 4010/4010A as the standard would result in impeding the expansion of EDI.

Moreover, if we continue to use Version 4010/4010A, the industry would continue to use a number of workarounds to be able to use the standards and would continue the reliance on companion guides, which is counter to the concept of standardization. The NCPDP testified to the NCVHS in July 2007 that adopting Version 5010 is a cost-saving measure that would improve the efficiency of those already using Version 4010/4010A, and encourage others to adopt and use more of the standards.

For Version D.0, we considered not adopting this modification and leaving intact the requirement to use Version 5.1. However, we rejected this alternative because we believe Version 5.1 has become outdated and is not efficient or effective in processing Medicare Part D prescription drug benefit program claims. We also considered waiting to adopt Version D.0 at a later date, but felt it was important to advance the use of Version D.0 to encourage standards adoption by the industry and enable the industry to reap the improved benefits of the standard as soon as possible.

For Medicaid subrogation transactions, we considered allowing the industry to continue using the proprietary formats currently in use. However, this would not have the desired effect of increasing the use of EDI, or of moving the industry towards a uniform standard.

With respect to the proposed adoption of the Version 3.0 Medicaid subrogation standard, we considered the following alternatives:

- Not adopt Version 3.0 and permit the industry to continue using Version 2.0 proprietary electronic and paper formats. This would require the Medicaid agencies to support multiple formats in order to bill pharmacy claims to third party payers. The current multiplicity of claim formats creates a significant barrier to Medicaid agencies being able to comply with Federal law in ensuring that Medicaid is the payer of last resort. Using the Version 2.0 standard would require a number of workarounds to be compatible with version D.0 or other NCPDP claim standards except for Version 5.1.
- The NCPDP testified to the NCVHS in January 2008 that adopting Version 3.0 for Medicaid subrogation is a cost-saving tool and would improve the efficiency of those already using Version 2.0. It also would make it more feasible for other states and payers to invest in system upgrades to accommodate one specific standard. The NCVHS did not recommend any viable alternatives to Version 3.0 for handling Medicaid subrogation transactions because they purported that Version 3.0 adequately addresses the business need for Medicaid agencies and industry partners.

Summary of Costs and Benefits for This Proposed Rule

The final tables, 27a and 27b, are the compilation of the minimum and maximum costs and benefits for all of the standards being proposed in this NPRM.

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Table 27a: Estimated minimum and maximum costs – in Millions* – for years 2010 through 2019 for Implementation of Versions 5010, D.0 and 3.0

Estimated minimum and maximum costs - in Millions* - for years 2010 through 2019 for Implementation of Versions 5010, D.0 and 3.0												
Cost Type	**Industry**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
5010 Implementation Costs	Hospitals - Minimum	$396	$396	$0	$0	$0	$0	$0	$0	$0	$0	$ 792
	Hospitals - Maximum	$792	$792	$0	$0	$0	$0	$0	$0	$0	$0	$1,584
	Physicians - Minimum	$185	$185	$0	$0	$0	$0	$0	$0	$0	$0	$370
	Physicians - Maximum	$370	$370	$0	$0	$0	$0	$0	$0	$0	$0	$740
	Dentists - Minimum	$127	$127	$0	$0	$0	$0	$0	$0	$0	$0	$254
	Dentists - Maximum	$254	$254	$0	$0	$0	$0	$0	$0	$0	$0	$508
	Pharmacy - Minimum	$29	$29	$0	$0	$0	$0	$0	$0	$0	$0	$58
	Pharmacy - Maximum	$57	$57	$0	$0	$0	$0	$0	$0	$0	$0	$114
	Private Health Plans - Minimum	1,532	$1,532	$0	$0	$0	$0	$0	$0	$0	$0	$3,064
	Private Health Plans - Maximum	3,064	$3,064	$0	$0	$0	$0	$0	$0	$0	$0	$6,128
	Government Health plans - Minimum	$107	$107	$0	$0	$0	$0	$0	$0	$0	$0	$214
	Government Health Plans - Maximum	$205	$204	$0	$0	$0	$0	$0	$0	$0	$0	$409

Estimated minimum and maximum costs - in Millions* - for years 2010 through 2019 for Implementation of Versions 5010, D.0 and 3.0												
Cost Type	**Industry**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
	Clearinghouses - Minimum	$17	$16	$0	$0	$0	$0	$0	$0	$0	$0	$33
	Clearinghouses - Maximum	$21	$20	$0	$0	$0	$0	$0	$0	$0	$0	$41
5010 Transition Costs	Hospital - Minimum	$0	$0	$140	$0	$0	$0	$0	$0	$0	$0	$140
	Hospitals - Maximum	$0	$0	$280	$0	$0	$0	$0	$0	$0	$0	$280
	Physicians - Minimum	$0	$0	$65	$0	$0	$0	$0	$0	$0	$0	$65
	Physicians - Maximum	$0	$0	$131	$0	$0	$0	$0	$0	$0	$0	$131
	Dentists - Minimum	$0	$0	$45	$0	$0	$0	$0	$0	$0	$0	$45
	Dentists - Maximum	$0	$0	$90	$0	$0	$0	$0	$0	$0	$0	$90
	Pharmacy - Minimum	$0	$0	$10	$0	$0	$0	$0	$0	$0	$0	$10
	Pharmacy - Maximum	$0	$0	$20	$0	$0	$0	$0	$0	$0	$0	$20
	Private Health Plan - Minimum	$0	$0	$541	$0	$0	$0	$0	$0	$0	$0	$541
	Private Health Plan - Maximum	$0	$0	$1,081	$0	$0	$0	$0	$0	$0	$0	$1,081
	Government Health Plan - Minimum	$0	$0	$38	$0	$0	$0	$0	$0	$0	$0	$38
	Government Health Plan - Maximum	$0	$0	$72	$0	$0	$0	$0	$0	$0	$0	$72
	Clearing-house - Minimum	$0	$0	$3	$0	$0	$0	$0	$0	$0	$0	$3
	Clearing-house - Maximum	$0	$0	$4	$0	$0	$0	$0	$0	$0	$0	$4
Medicaid Subrogation - Development	Federal - Minimum	$.158	$.158	$0	$0	$0	$0	$0	$0	$0	$0	$ .316
	Federal - Maximum	$.472	$.472	$0	$0	$0	$0	$0	$0	$0	$0	$ .944
	State - Minimum	.018	$ .018	$0	$0	$0	$0	$0	$0	$0	$0	$ .036
	State - Maximum	.052	$ .052	$0	$0	$0	$0	$0	$0	$0	$0	$ .104
	Payers - Minimum	$.500	$.500	$0	$0	$0	$0	$0	$0	$0	$0	$1
	Payers - Maximum	$1.5	$1.5	$0	$0	$0	$0	$0	$0	$0	$0	$3
Medicaid Subrogation - Trading Partner	Federal - Minimum	$.191	$.191	$0	$0	$0	$0	$0	$0	$0	$0	$.382

Estimated minimum and maximum costs - in Millions* - for years 2010 through 2019 for Implementation of Versions 5010, D.0 and 3.0

Cost Type	Industry	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Agreements												
	Federal - Maximum	$.580	$.580	$0	$0	$0	$0	$0	$0	$0	$0	$1.160
	State - Minimum	$.191	$.191	$0	$0	$0	$0	$0	$0	$0	$0	$ .382
	State - Maximum	$.580	$.580	$0	$0	$0	$0	$0	$0	$0	$0	$1.160
	Payers - Minimum	$1.2	$1.2	$0	$0	$0	$0	$0	$0	$0	$0	$2.4
	Payers - Maximum	$3.6	$3.6	$0	$0	$0	$0	$0	$0	$0	$0	$7.2
D.0 - Pharmacy Chains Systems Implementation	Pharmacy - Minimum	$9	$9	$0	$0	$0	$0	$0	$0	$0	$0	$18
	Pharmacy - Maximum	$19	$19	$0	$0	$0	$0	$0	$0	$0	$0	$38
Independent Pharmacy Maintenance Fees	Pharmacy - Minimum	$.270	$.270	$0	$0	$0	$0	$0	$0	$0	$0	$.540
	Pharmacy - Maximum	$.540	$.540	$0	$0	$0	$0	$0	$0	$0	$0	$1.080
PBM Programming	PBM-Minimum	$4	$4	$0	$0	$0	$0	$0	$0	$0	$0	$8
	PBM-Maximum	$5	$5	$0	$0	$0	$0	$0	$0	$0	$0	$10
Total - Minimum		**$2,409**	**$2,406**	**$842**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$5,656**
Total - Maximum		**$4,793**	**$4,786**	**$1,678**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$11,257**

Table 27b: Estimated minimum and maximum benefits – in Millions* – for years 2010 through 2019 for Implementation of Version 5010. D.0 and Version 3.0

Estimated minimum and maximum benefits - in Millions* - for years 2010 through 2019 for Implementation of Version 5010. D.0 and Version 3.0												
Benefit Type	**Industry**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
5010 Operational Savings - Better Standards	Hospitals - Minimum	$0	$0	$44	$46	$47	$49	$51	$53	$55	$58	$403
	Hospitals - Maximum	$0	$0	$119	$124	$129	$134	$139	$145	$150	$156	$1,095
	Physicians - Minimum	$0	$0	$175	$182	$189	$197	$205	$213	$221	$230	$1,612
	Physicians - Maximum	$0	$0	$475	$494	$514	$535	$556	$578	$601	$625	$4,378
	Dentists - Minimum	$0	$0	$30	$31	$32	$33	$35	$36	$38	$39	$274
	Dentists - Maximum	$0	$0	$76	$79	$82	$85	$89	$92	$96	$100	$699
	Pharmacy - Minimum	$0	$0	$2	$2	$2	$2	$3	$3	$3	$3	$20
	Pharmacy - Maximum	$0	$0	$3	$3	$3	$3	$3	$4	$4	$4	$27
	Private and Govt. Health Plans - Minimum	$0	$0	$169	$176	$183	$191	$198	$206	$214	$223	$1,560
	Private and Govt. Health Plans - Maximum	$0	$0	$453	$471	$490	$510	$530	$551	$573	$596	$4,174
	Clearinghouses - Minimum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Clearinghouses - Maximum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
5010 Cost Savings - Increase in transactions	Hospital - Minimum	$0	$0	$2	$4	$6	$8	$11	$11	$12	$12	$67
	Hospital - Maximum	$0	$0	$6	$13	$20	$28	$36	$37	$39	$40	$219
	Physicians - Minimum	$0	$0	$8	$16	$24	$34	$44	$46	$48	$50	$270
	Physicians - Maximum	$0	$0	$25	$51	$80	$110	$143	$149	$155	$161	$874
	Dentists - Minimum	$0	$0	$1	$3	$4	$6	$7	$8	$8	$8	$45
	Dentists -	$0	$0	$2	$3	$5	$7	$9	$10	$10	$10	$56

Estimated minimum and maximum benefits - in Millions* - for years 2010 through 2019 for Implementation of Version 5010. D.0 and Version 3.0											
Benefit Type	**Industry**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
	Maximum											
	Pharmacy - Minimum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Pharmacy - Maximum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Private and Govt. Health Plans - Minimum	$0	$0	$9	$13	$17	$18	$18	$19	$20	$21	$135
	Private and Govt. Health Plans - Maximum	$0	$0	$24	$33	$43	$44	$46	$48	$50	$52	$340
	Clearinghouses - Minimum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Clearinghouses - Maximum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
5010 Operational Savings - increase in auxiliary claim transactions	Hospital - Minimum	$0	$0	$35	$74	$117	$165	$217	$226	$235	$245	$1,314
	Hospital - Maximum	$0	$0	$90	$191	$303	$428	$566	$588	$612	$636	$3,414
	Physicians - Minimum	$0	$0	$139	$294	$467	$658	$870	$904	$941	$978	$5,251
	Physicians - Maximum	$0	$0	$361	$765	$1213	$1711	$2261	$2352	$2446	$2543	$13,652
	Dentists - Minimum	$0	$0	$24	$50	$79	$111	$147	$153	$159	$166	$889
	Dentists - Maximum	$0	$0	$58	$122	$193	$272	$360	$374	$389	$405	$2,173
	Pharmacy - Minimum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Pharmacy - Maximum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
	Private and Government Health Plans - Minimum	$0	$0	$141	$299	$474	$669	$885	$920	$957	$995	$5,340
	Private and Government Health Plans - Maximum	$0	$0	$367	$777	$1233	$1740	$2300	$2392	$2488	$2587	$13,885
	Clearinghouse - Minimum	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Medicaid Subrogation - General Benefit	Federal - Minimum	$1.16	$2.33	$4.7	$4.7	$0	$0	$0	$0	$0	$0	$12.9
	Federal - Maximum	$1.59	$3.20	$6.4	$6.4	$0	$0	$0	$0	$0	$0	$17.6
	State - Minimum	$1.16	$2.33	$4.7	$4.7	$0	$0	$0	$0	$0	$0	$12.9
	State - Maximum	$1.59	$3.20	$6.4	$6.4	$0	$0	$0	$0	$0	$0	$17.6
	Payer - Minimum	$.600	$1.24	$2.475	$2.475	$0	$0	$0	$0	$0	$0	$6.8

Estimated minimum and maximum benefits - in Millions* - for years 2010 through 2019 for Implementation of Version 5010. D.0 and Version 3.0												
Benefit Type	Industry	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
	Payer - Maximum	$.800	$1.65	$3.3	$3.3	$0	$0	$0	$0	$0	$0	$9.05
D.0 Pharmacist Productivity	Pharmacist -Minimum	$84	$90	$96	$102	$109	$115	$122	$130	$139	$148	$1,135
	Pharmacist - Maximum	$166	$179	$191	$203	$217	$229	$244	$260	$278	$296	$2,268
D.0 Pharmacy Technician Productivity Savings	Pharmacy - Minimum	$9	$9	$9	$9	$10	$10	$10	$10	$11	$11	$98
	Pharmacy - Maximum	$17	$18	$18	$19	$19	$20	$20	$21	$22	$22	$196
D.0 Avoided Audits and Accurate Payments	Pharmacy - Minimum	$19	$19	$19	$19	$19	$19	$19	$19	$19	$19	$190
	Pharmacy - Maximum	$38	$38	$38	$38	$38	$38	$38	$38	$38	$38	$380
TOTAL - Minimum		$115	$124	$915	$1,332	$1,779	$2,285	$2,842	$2,957	$3,080	$3,206	$18,635
TOTAL - Maximum		$225	$243	$2,332	$3,402	$4,492	$5,894	$7,340	$7,639	$7,951	$8,271	$47,779

BILLING CODE 4120–01–C

E. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement. This statement must state that we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Monetary annualized Benefits and non-budgetary costs are presented as discounted flows using three percent and seven percent factors.

TABLE 28—ACCOUNTING STATEMENT

[Accounting Statement: Classification of Estimated Expenditures, from FY 2010 to FY 2019 (in millions)]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
Benefits				
Annualized Monetized benefits:				
7% Discount	$2,930	$1,647	$4,214	RIA.
3% Discount	$3,151	$1,769	$4,532	RIA.
Qualitative (un-quantified) benefits	Wider adoption of standards due to decrease in use of companion guides; increased productivity due to decrease in manual intervention requirements.			
Benefits generated from plans to providers and pharmacies, providers to plans and pharmacies, and pharmacies to beneficiaries.				
Costs				
Annualized Monetized costs:				
7% Discount	$1,073	$718	$1,428	RIA.
3% Discount	$942	$630	$1,254	RIA.
Qualitative (un-quantified) costs	None	None	None.	
Cost will be paid by health plans to contractors, programming consultants, IT staff and other outsourced entities; providers will pay costs to software vendors, trainers and other consultants. Clearinghouses will pay costs to IT staff/contractors and software developers; pharmacies will pay costs to contractors, software vendors and trainers, and government plans will pay costs to consultants, vendors and staff.				
Transfers				
Annualized monetized transfers: ''on budget''.	N/A	N/A	N/A.	
From whom to whom?	N/A	N/A	N/A.	
Annualized monetized transfers: ''off-budget''.	N/A	N/A	N/A.	
From whom to whom?	N/A	N/A	N/A.	

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

List of Subjects in 45 CFR Part 162

Administrative practice and procedure, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicare, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter C as set forth below:

PART 162—ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

Authority: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–1320d–8), as added by sec. 262 of Public Law 104–191, 110 Stat. 2021–2031, and sec. 264 of Public Law 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

Subpart I—General Provision for Transactions

2. Revise § 162.900 to read as follows:

§ 162.900 Compliance dates for transaction standards and code sets.

(a) *Small health plans.* (1) All small health plans must comply with the applicable requirements of Subparts I through R of this part no later than October 16, 2003.

(2) All small health plans must comply with the applicable requirements of Subpart S of this part no later than [date 36 months after the effective date of the final rule].

(b) Covered entities other than small health plans.

(1) All covered entities other than small health plans must comply with the applicable requirements of Subparts I through R of this part no later than October 16, 2003.

(2) All covered entities other than small health plans must comply with the applicable requirements of Subpart S of this part no later than [date 24 months after the effective date of the final rule].

3. Amend § 162.920 as follows:

A. Revise the introductory text and paragraph (a) introductory text.

B. Add paragraphs (a)(10) through (a)(18).

C. Revise paragraph (b) introductory text.

D. Add paragraphs (b)(4) through (b)(6).

The revisions and additions read as follows:

§ 162.920 Availability of implementation specifications.

A person or an organization may directly request copies of the implementation specifications and the Technical Reports Type 3 described in subparts I through S of this part from the publishers listed in this section. The Director of the Federal Register approves the implementation specifications, which include the Technical Reports Type 3 described in this section for incorporation by reference in subparts I through S of this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The implementation specifications and Technical Reports Type 3 described in this section are also available for inspection by the public at the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–714–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/i br_locations.html.*

(a) *ASC X12N specifications and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3.* The implementation specifications for the ASC X12N and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 (and accompanying Type 1 Errata) may be obtained from the Washington Publishing Company, 747 177th Lane, NE., Bellevue, WA, 98008; Telephone (425) 562–2245; and FAX (775) 239–2061. They are also available through the Internet at *http://www.wpc-edi.com/.* All ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 adopted for use under HIPAA and any corresponding addenda are available in three configurations: downloadable PDFs, PDFs shipped on CD, and bound books. A fee is charged for all implementation specifications, including Technical Reports. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

* * * * *

(10) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, Washington Publishing Company, 005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X224A1, as referenced in § 162.1102 and § 162.1802.

(11) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, Washington Publishing Company, 005010X222, as referenced in § 162.1102 and § 162.1802.

(12) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, Washington Publishing Company, 005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X223A1, as referenced in § 162.1102 and § 162.1802.

(13) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, Washington Publishing Company, 005010X221, as referenced in § 162.1602.

(14) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, Washington Publishing Company, 005010X220, as referenced in § 162.1502.

(15) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, Washington Publishing Company, 005010X218, as referenced in § 162.1702.

(16) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, Washington Publishing Company, 005010X217, and Type 1 Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, Washington Publishing Company, 005010X217E1, as referenced in § 162.1302.

(17) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, Washington Publishing Company, 005010X212, and Type 1 Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, Washington Publishing Company (005010X212E1), as referenced in § 162.1402.

(18) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, Washington Publishing Company, 005010X279, as referenced in § 162.1202.

(b) *Retail pharmacy specifications and Medicaid subrogation implementation guides.* The implementation specifications for the retail pharmacy standards and the implementation specifications for the batch standard for Medicaid subrogation transactions may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477–1000; FAX (480) 767–1042. They are also available through the internet at *http://www.ncpdp.org.* A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

* * * * *

(4) The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(5) The Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(6) The Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902.

4. Revise § 162.923 paragraph (a) to read as follows:

§ 162.923 Requirements for covered entities.

(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts with another covered entity that is required to comply with a transaction standard adopted under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.

* * * * *

Subpart K—Health Care Claims or Equivalent Encounter Information

5. Section 162.1102 is amended as follows:

A. Revise the introductory text to paragraph (b).

B. Add a new paragraph (c).

The revisions and additions read as follows:

§ 162.1102 Standards for health care claims or equivalent encounter information transaction.

* * * * *

(b) For the period from October 16, 2003 through March 31, 2010:

* * * * *

(c) For the period on and after April 1, 2010:

(1) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, Washington Publishing Company, 005010X224, and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X224A1. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, Washington Publishing Company, 005010X222. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, Washington Publishing Company, 005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X223A1. (Incorporated by reference in § 162.920).

(5) *Retail pharmacy supplies and professional services claims.* (i) The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs (Incorporated by reference in § 162.920); and

(ii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, Washington Publishing Company, 005010X222. (Incorporated by reference in § 162.920).

Subpart L—Eligibility for a Health Plan

6. Section 162.1202 is amended by—

A. Revising the introductory text to paragraph (b).

B. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 162.1202 Standards for eligibility for a health plan transaction.

* * * * *

(b) For the period from October 16, 2003 through March 31, 2010:

* * * * *

(c) For the period on and after April 1, 2010:

(1) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, Washington Publishing Company, 005010X279. (Incorporated by reference in § 162.920).

Subpart M—Referral Certification and Authorization

7. Revise § 162.1301 to read as follows:

§ 162.1301 Referral certification and authorization transaction.

The referral certification and authorization transaction is any of the following transmissions:

(a) A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care.

(b) A request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider.

(c) A response from a health plan to a health care provider to a request described in paragraph (a) or paragraph (b) of this section.

8. Section 162.1302 is amended by—

A. Revising the introductory text to paragraph (b).

B. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 162.1302 Standards for referral certification and authorization transaction.

* * * * *

(b) For the period from October 16, 2003 through March 31, 2010:

* * * * *

(c) For the period on and after April 1, 2010:

(1) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional request for review and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, Washington Publishing Company (005010X217), and Type 1 Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, Washington Publishing Company, 005010X217E1. (Incorporated by reference in § 162.920).

Subpart N—Health Care Claim Status

9. Revise § 162.1401 to read as follows:

§ 162.1401 Health care claim status transaction.

The health care claim status transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan to determine the status of a health care claim.

(b) A response from a health plan to a health care provider about the status of a health care claim.

10. Section 162.1402 is amended by—

A. Removing ''on and after October 16, 2003'' and adding in its place ''from October 16, 2003 through March 31, 2010'' in the introductory text in paragraph (b).

B. Adding a new paragraph (c).

The additions read as follows:

§ 162.1402 Standards for health care claim status transaction.

* * * * *

(c) For the period on and after April 1, 2010: The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, Washington Publishing Company, 005010X212, and Type 1 Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, Washington Publishing Company, 005010X212E1. (Incorporated by reference in § 162.920).

Subpart O—Enrollment and Disenrollment in a Health Plan

11. Revise § 162.1501 to read as follows:

§ 162.1501 Enrollment and disenrollment in a health plan transaction.

The enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information from the sponsor of the insurance coverage, benefits, or policy, to a health plan to establish or terminate insurance coverage.

12. Section 162.1502 is amended by—

A. Removing ''on and after October 16, 2003'' and adding in its place ''from October 16, 2003 through March 31, 2010'' in the introductory text of paragraph (b).

B. Adding a new paragraph (c).

The additions read as follows:

§ 162.1502 Standards for enrollment and disenrollment in a health plan transaction.

* * * * *

(c) For the period on and after April 1, 2010: The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, Washington Publishing Company, 005010X220 (Incorporated by reference in § 162.920).

Subpart P—Health Care Payment and Remittance Advice

13. Section 162.1602 is amended by—

A. Removing ''on and after October 16, 2003'' and adding in its place ''from October 16, 2003 through March 31, 2010'' in the introductory text of paragraph (b).

B. Adding a new paragraph (c).

The additions read as follows:

§ 162.1602 Standards for health care payment and remittance advice transaction.

* * * * *

(c) For the period on and after April 1, 2010: The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, Washington Publishing Company, 005010X221. (Incorporated by reference in § 162.920).

Subpart Q—Health Plan Premium Payments

14. Section 162.1702 is amended by—

A. Removing ''on and after October 16, 2003'' and adding in its place ''from October 16, 2003 through March 31, 2010'' in the introductory text of paragraph (b).

B. Adding a new paragraph (c).

The additions read as follows:

§ 162.1702 Standards for health plan premium payments transaction.

* * * * *

(c) For the period on and after April 1, 2010: The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, Washington Publishing Company, 005010X218. (Incorporated by reference in § 162.920).

Subpart R—Coordination of Benefits

15. Section 162.1802 is amended by—

A. Revising the introductory text of paragraph (b).

B. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 162.1802 Standards for coordination of benefits information transaction.

* * * * *

(b) For the period from October 16, 2003 through March 31, 2010:

* * * * *

(c) For the period on and after April 1, 2010:

(1) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920).

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, Washington Publishing Company, 005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X224A1. (Incorporated by reference in § 162.920).

(3) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, Washington Publishing Company, 005010X222. (Incorporated by reference in § 162.920).

(4) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, Washington Publishing Company, 005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X223A1. (Incorporated by reference in § 162.920).

16. Add a new Subpart S to read as follows:

Subpart S—Medicaid Pharmacy Subrogation

Sec.

162.1901 Medicaid pharmacy subrogation transaction.
162.1902 Standard for Medicaid pharmacy subrogation.

§ 162.1901 Medicaid pharmacy subrogation transaction.

The Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the State has paid on behalf of a Medicaid recipient.

§ 162.1902 Standard for Medicaid pharmacy subrogation.

The Secretary adopts the Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902. (Incorporated by reference at § 162.920).

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 23, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 14, 2008.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on August 15, 2008.

[FR Doc. E8–19296 Filed 8–15–08; 3:55 pm]

BILLING CODE 4120–01–P

Federal Register

Friday,
August 22, 2008

Part III

Department of Health and Human Services

Office of the Secretary

45 CFR Parts 160 and 162

HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 162

[CMS–0013–P]

RIN 0958–AN25

HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS

AGENCY: Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would modify two of the medical data code set standards adopted in the Transactions and Code Sets final rule published in the **Federal Register**. It would also implement certain provisions of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Specifically, the proposed rule would modify the standard code sets for coding diagnoses and inpatient hospital procedures by concurrently adopting the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) for diagnosis coding, and the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding. These new codes would replace the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) Volumes 1 and 2, and the International Classification of Diseases, Ninth Revision, Clinical Modification (CM) Volume 3 for diagnosis and procedure codes, respectively.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 21, 2008.

ADDRESSES: In commenting, please refer to file code CMS–0013–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov,* accessed 8–12–08. Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0013–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0013–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or (Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–8016.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

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

FOR FURTHER INFORMATION CONTACT: Donna Pickett (301) 458–4434 for ICD–10–CM, Pat Brooks (410) 786–5318 for ICD–10–PCS, and Denise Buenning (410) 786–6711 for other questions.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov,* accessed 8–12–08. Follow the search instructions on that Web site to view public comments.

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

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I. Background

A. Statutory Background

The Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, enacted on August 21, 1996. HIPAA has improved the Medicare and Medicaid programs and the efficiency and effectiveness of the health care system in general, by encouraging the development of standards and requirements to facilitate the electronic transmission of certain health information.

Through subtitle F of title II of that statute, the Congress added to title XI of the Social Security Act (the Act) a new Part C, titled ''Administrative Simplification.'' Part C of title XI of the Act consists of sections 1171 through 1179. Section 1172 of the Act and the implementing regulations make any standard adopted under Part C applicable to: (1) Health plans; (2) health care clearinghouses; and (3) health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard.

Section 1172(c)(1) of the Act requires any standard adopted by the Secretary of the Department of Health and Human Services (the Secretary) to be developed, adopted, or modified by a standard setting organization (SSO), except in the special cases identified under section 1172(c)(2) of the Act. Under section 1172(c)(2)(A) of the Act, the Secretary may adopt a standard that is different from any standard developed by an SSO if it will substantially reduce administrative costs to health care providers and health plans compared to the alternatives, and the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of Title 5 of the United States Code. Under section 1172(c)(2)(B) of the Act, if no SSO has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt, section 1172(c)(1) does not apply.

Section 1172 of the Act also sets forth consultation requirements that must be met before the Secretary may adopt standards. The SSO must consult with the following Data Content Committees (DCCs) in the course of the development, adoption, or modification of the standard: the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA). For a standard that was not developed by an SSO, the Secretary is required to consult with each of the above-named groups before adopting the standard. Under section 1172(f) of the Act, the Secretary must also rely on the recommendations of the National Committee on Vital and Health Statistics (NCVHS) and consult with appropriate Federal and State agencies and private organizations.

Section 1173(a) of the Act requires the Secretary to adopt transaction standards and data elements for the electronic exchange of health information for certain health care transactions. Under sections 1173(b) through (f) of the Act, the Secretary is required to adopt standards for: unique health identifiers, code sets, security standards for health information, electronic signatures, and the transfer of information among health plans.

Section 1174 of the Act permits the Secretary to review the adopted standards and adopt modifications as appropriate, but not more frequently than once every 12 months in a manner which minimizes disruption and cost of compliance. The same section requires the Secretary to ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets, along with instructions on how data elements encoded before any modification may be converted or translated to preserve the information value of any pre-existing data elements.

Section 1175(b) of the Act provides for a compliance date not later than 24 months after the date on which an initial standard or implementation specification is adopted for all covered entities except small health plans, for which the statute provides for a compliance date not later than 36 months after the date on which an initial standard or implementation specification is adopted. If the Secretary adopts a modification to a HIPAA standard or implementation specification, the compliance date for the modification may not be earlier than the 180th day following the effective date of the adoption of the modification. The Secretary may consider the nature and extent of the modification when determining compliance dates. The Secretary may extend the time for compliance for small health plans. We are proposing that the compliance date for the provisions of this proposed rule for all covered entities, including small health plans, would be October 1, 2011.

Please refer to the Transactions and Code Sets final rule (65 FR 50312), published in the **Federal Register** on August 17, 2000, and the Privacy Rule (65 FR 82462), published in the **Federal Register** on December 28, 2000, for further information about electronic data interchange and the statutory background.

B. Regulatory Background: Adoption and Modification of HIPAA Code Sets

The Transactions and Code Sets final rule appeared in the August 17, 2000 **Federal Register** (65 FR 50312). That rule implemented some of the requirements of the Administrative Simplification subtitle of HIPAA, by adopting standards for eight electronic transactions for use by covered entities (health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard). We established these standards at 45 CFR parts 160, subpart A, and 162, subparts A, and I through R. The Transactions and Code Sets Modifications final rule, published on February 20, 2003 (68 FR 8381), modified the implementation specifications for several adopted transactions standards, among other provisions. (Please refer to the HIPAA Transactions and Code Sets final rule and HIPAA Transactions and Code Sets

Modifications final rule for detailed discussions of electronic data interchange and an analysis of the public comments received during the promulgation of both rules).

In the Transactions and Code Sets final rule, we also adopted a number of standard medical data code sets for use in those transactions, including:

- International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) Volumes 1 and 2 (including the Official ICD–9–CM Guidelines for Coding and Reporting) as maintained and distributed by HHS, for coding diseases, injuries, impairments, other health problems and their manifestations, and causes of injury, disease, impairment, or other health problems.
- ICD–9–CM Volume 3 (including the Official ICD–9–CM Guidelines for Coding and Reporting) as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals: prevention, diagnosis, treatment, and management.

ICD–9–CM Volumes 1 and 2, and 3 were already widely used in administrative transactions when we promulgated the Transactions and Code Sets rule. We decided that adopting these existing code sets would be less disruptive for covered entities than modified or new code sets. In the Transactions and Code Sets final rule (65 FR 50327), we discussed comments on using the ICD–10–CM and ICD–10–PCS code sets as future HIPAA standard medical data code sets. Some commenters praised the accuracy of the ICD–10–CM and ICD–10–PCS code sets, others raised concerns about the differences between the ICD–9–CM and ICD–10–CM and ICD–10–PCS code sets, including the increased level of detail in ICD–10–PCS. We responded that additional testing and revision were needed before adopting the ICD–10–CM and ICD–10–PCS code sets as a standard. (Please refer to the Transactions and Code Sets final rule for details of that discussion (65 FR 50327).)

In addition to standard transactions and code sets, the final rule adopted a procedure for maintaining existing standards, for adopting modifications to existing standards, and for adopting new standards. Our process in proposing the adoption of ICD–10–CM and ICD–10–PCS, to replace ICD–9–CM Volumes 1 and 2, and 3, follows that procedure. The following is a summary of the consultation requirements for the Secretary for the adoption of standards under sections 1172(b) through (f) of the Act:

For standards that have been developed, adopted, or modified by a standard setting organization, the SSO must consult with the following organizations in the course of such development, adoption, or modification:

- The National Uniform Billing Committee (NUBC).
- The National Uniform Claim Committee (NUCC).
- The Workgroup for Electronic Data Interchange (WEDI).
- The American Dental Association (ADA).

For any other standards, the Secretary is required to consult with these same organizations.

As part of the HIPAA modification and update process, the NCVHS holds hearings on proposed changes to HIPAA transaction and code set standards and makes recommendations to the Secretary as appropriate.

Under section 1174 of the Act, the Secretary must also ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets, and provide instructions on how data elements encoded before any modification may be converted or translated. As discussed in section VIII.A of this proposed rule, we will establish an ICD–10–CM/PCS Coordination and Maintenance Committee that is similar to the ICD–9–CM Coordination and Maintenance Committee. The ICD–10–CM/PCS Coordination and Maintenance Committee will be charged with routine maintenance, testing, enhancement, and the expansion of the ICD–10 code sets. In addition, the National Center for Health Statistics (NCHS) has recently completed a crosswalk that maps ICD–9–CM Volumes 1 and 2 to ICD–10–CM. CMS also has developed a crosswalk that maps ICD–9–CM Volume 3 to ICD–10–PCS. These crosswalks are available at *http://www.cms.hhs.gov/ICD10* (accessed 8–12–08) and *http://www.cdc.gov/nchs/about/otheract/icd9/icd10cm.htm,* (accessed 8–12–08). These crosswalks are revised in the fall of each year.

II. ICD–9–CM

The International Classification of Diseases (ICD) is developed and maintained by the World Health Organization (WHO). Originally designed to classify causes of death (mortality), the scope of the ICD has expanded to include non-fatal diseases (morbidity). The application of the classification to morbidity has expanded as the code set has been revised. Nonetheless, the United States and other countries continue to find it necessary to develop clinical modifications of the ICD to meet the needs of their respective health care systems that include administrative and clinical protocols, and require more detail and specificity for reporting health care.

When the Medicare hospital Inpatient Prospective Payment System (IPPS) was implemented in 1983, ICD–9–CM was used as the basic input for assigning the diagnosis-related groups (DRGs). All diagnostic and procedural information was captured using ICD–9–CM.

A. ICD–9–CM Volumes 1 and 2 (Diagnoses)

NCHS houses the WHO Collaborating Center for the Family of International Classifications for North America (United States and Canada), and has responsibility for the implementation of the ICD. NCHS produced a clinical modification to WHO's ICD–9 by adding more specificity to its diagnosis codes (ICD–9–CM Volumes 1 and 2). ICD–9–CM maps to ICD to facilitate comparison of mortality and morbidity statistics. ICD–9–CM was adopted in the United States in 1979 for morbidity applications, and was adopted as a HIPAA standard in 2000 for reporting diagnoses, injuries, impairments, and other health problems and their manifestations, and causes of injury, disease, impairment or other health problems in standard transactions. ICD–9–CM diagnosis codes are three to five digits long, and are used by all types of health care providers, including hospitals and physician practices. The code set is organized into chapters by body system.

B. ICD–9–CM Volume 3 (Procedures)

Inpatient hospital services procedures are currently coded using ICD–9–CM Volume 3. The WHO's ICD does not include procedure codes. ICD–9–CM procedure codes are three to four digits long. The code set was adopted as a HIPAA standard in 2000 for reporting inpatient hospital procedures. Current Procedural Terminology, 4th Edition (CPT–4) and Health Care Common Procedure Coding System (HCPCS) are used to code all other procedures. The ICD–9–CM procedure code set is organized into chapters by body system, and CMS maintains the ICD–9–CM procedure codes.

C. Maintaining/Updating ICD–9–CM (Volumes 1 and 2, and 3)

Recognizing the need for ICD–9–CM to be a flexible, dynamic statistical tool to meet expanding classification needs, the ICD–9–CM Coordination and

Maintenance Committee was created in 1985 as a forum for receiving public comments on proposed code revisions, deletions, and additions. The Committee is co-chaired by the NCHS and CMS; NCHS maintains ICD–9–CM Diagnosis Codes (Volumes 1 and 2), and CMS maintains ICD–9–CM Procedure Codes (Volume 3).

Although the ICD–9–CM Coordination and Maintenance Committee is a Federal committee, suggestions for updates come from both the public and private sectors. Interested parties may submit recommendations for updates (that is, adding new codes, deleting codes, and editing descriptive material related to existing codes) at least 2 months before a scheduled meeting. Proposals for a new code must include a description of the code being requested and rationale for why the new code is needed. Supporting references and literature may also be submitted.

This Federal committee meets in March and September. Decisions on code title revisions are made by March for inclusion in the annual IPPS proposed rule. Updates on codes, payments, and reporting systems are finalized after the previous fall meeting and may become effective October 1 of the same year.

Section 503(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) included a requirement for updating ICD–9–CM codes twice a year, instead of a single update on October 1 of each year. Section 503(a) of the MMA, which amended section 1886(d)(5)(K) of the Act, states that the ''Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) * * * until the fiscal year that begins after such date.'' By adding codes for a new technology at an earlier date, CMS can recognize the new technology more quickly for purposes of payment under the IPPS.

While section 503(a) of the MMA does not require the Secretary to adjust the DRG classification and payments until the subsequent fiscal year, the DRG software and other systems must be updated to recognize and accept the new codes, and providers must update their systems mid-year to capture the new codes. Hospitals must obtain coding book updates and coding software updates and make other system changes to capture and report the new codes.

Proposals for new and revised codes, summaries of meetings, information about deadlines for comment, scheduled dates for the next meeting, deadlines for receipt of maintenance proposals, and mailing and e-mail addresses are posted to the CMS Web site at *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes,* accessed 8–12–08, and the NCHS Web site *http://www.cdc.gov/nchs/icd9.htm,* accessed 8–12–08. Additionally, CMS and NCHS publish a complete addendum describing details of all changes to ICD–9–CM. It is publicized on their Web sites in May of each year. Many commenters on the proposed Transactions and Code Sets proposed rule commended this open process (65 FR 50343–50344).

III. Limitations of ICD–9–CM

A. Background

In 1997, the NCVHS began to study the issues related to known shortcomings of ICD–9–CM and to assess the need to transition to ICD–10 (or an alternative code set), including the impact of such a transition. The NCVHS has conducted more than 8 days of hearings since 1997. Oral and written testimony was provided by more than 80 public and private sector groups representing the health care industry, Federal and State governments, the public health and research communities, health plans, and health care providers. In addition, the NCVHS commissioned a RAND Corporation study on the potential costs and benefits of transitioning to ICD–10–CM and ICD–10–PCS. From the testimony received and the RAND study findings, NCVHS concluded that ICD–10–CM and ICD–10–PCS should be adopted as a HIPAA standard to replace the current standard, ICD–9–CM Volumes 1 and 2, and 3. In a letter to the Secretary dated November 5, 2003, NCVHS recommended that HHS initiate the regulatory process for the concurrent adoption of ICD–10–CM and ICD–10–PCS. The NCVHS letter (*http://www.ncvhs.hhs.gov/031105lt.htm*) accessed 8–12–08, an overview of the development of ICD–10–CM and ICD–10–PCS (*http://www.ncvhs.hhs.gov/031105a1.htm*) accessed 8–12–08, summaries of the NCVHS activities (*http://www.ncvhs.hhs.gov/031105a2.htm*) accessed 8–12–08, a list of organizations that have provided testimonies (*http://www.ncvhs.hhs.gov/031105a3.htm*) accessed 8–12–08, and the RAND Corporation study (*http://www.rand.org/pubs/technical_reports/2004/RAND_TR132.pdf*) are available on the NCVHS Web site (*http://www.ncvhs.hhs.gov*) accessed 8–12–08.

B. General

The ICD–9–CM code set has been in use for over 27 years, and additional codes have been added during that period to describe new procedures and diagnoses that reflect changes in medical practice. The total number of codes (approximately 13,000 for diagnoses and 3,000 for procedures) is insufficient to continue to respond to the need for new codes. Moreover, the code set was never designed to provide the increased level of detail needed to support emerging needs, such as biosurveillance and pay-for-performance programs (P4P), also known as value-based purchasing or competitive purchasing. These limitations are discussed in detail below and have led to the current industry debate regarding replacement of ICD–9–CM. Industry experts have discussed and commented on these issues during testimony to the NCVHS, expressing their belief that the ICD–9–CM code set is nearing the end of its useful life. We invite public comment on concerns with continued use of the ICD–9–CM code set.

1. Space Limitations

The ICD–9–CM code set that we adopted in 2000 as a HIPAA standard had been evolving since 1979. Because of the new and changing medical advancements during the past 20 plus years, the functionality of the ICD–9–CM code set has been exhausted. This code set is no longer able to respond to additional classification specificity, newly identified disease entities, and other advances. Many chapters of ICD–9–CM are full, and the American Hospital Association (AHA) has estimated that we will run out of procedure codes in the appropriate, logical sections of ICD–9–CM as well as the overflow chapters in 2009. As a temporary solution, CMS has already begun to assign codes to the inappropriate sections of ICD–9–CM (for example, codes for heart procedures being placed in the eye chapter). We will continue to take this unusual step of making illogical code assignments in order to maintain the ability to capture emerging technologies. This illogical assignment of codes will lead to challenges for coders in identifying and assigning codes, but establishing new codes to identify new procedures remains important. The diagnosis-related group (DRG) system classifies hospital cases into groups that are expected to have similar hospital resource needs. DRGs are assigned

based on diagnoses, procedures, age, sex, and the presence of complications or co-morbidities.

The technologies included in the DRGs are identified by ICD–9–CM procedure codes. ICD–10–PCS allows the use of DRG definitions that better define new technologies and devices, and that could be refined to take advantage of their additional specificity through more detailed descriptions. This critical lack of space for new procedures and conditions is one important consideration for proposing to adopt ICD–10–CM and ICD–10–PCS. In addition, ICD–9–CM's space limitations are creating other problems, which are discussed below.

2. Impact of Workarounds on Structural Hierarchy

The hierarchical structure of the ICD–9–CM procedure code set is compromised. Some chapters can no longer accommodate new codes, with the result that any additional codes must be assigned to other topically unrelated chapters. For example, new hip replacement procedures must now be assigned to an ''overflow'' chapter for procedures that are not classified elsewhere. When those chapters become full, new procedures would have to be assigned to a chapter now devoted to procedures related to the eye. When a code is isolated in a separate, unrelated part of the ICD–9–CM book because there is no available space in the section where the code normally would be assigned, coders may not easily find the code. Researchers and statisticians also may miss cases in their analyses.

3. Lack of Detail

Industry experts have pointed out that in an age of electronic health records, it does not make sense to use a coding system that lacks specificity and does not lend itself well to updates. Another consideration about the limitations of ICD–9–CM is that to generate meaningful research results, researchers need to have access to comprehensive, rich data with a level of detail that does not exist with ICD–9–CM. Emerging health care technologies, new and advanced terminologies, and the need for interoperability amid the increase in electronic health records (EHRs) and personal health records (PHRs) require a standard code set that is expandable and sufficiently detailed to accurately capture current and future health care information. Coding that accurately describes diagnoses and procedures will capture information that is critical for research, and ultimately improves the quality of health care and cost containment by enabling the study of specific conditions and options for treating them. Accuracy also is a critical factor in the development of Pay for Performance (P4P) programs, because successful programs require detailed coding of diagnoses and the procedures performed to treat specific conditions.

The details for advanced technology procedures currently being performed today were not available when ICD–9–CM was being developed. Numerous ICD–9–CM procedure codes are based upon technology that is now outdated. As we move toward more sophisticated monitoring and quality reporting, this level of detail when reporting diagnoses and procedures becomes critical. Examples are noted below:

- ICD–9–CM has a single diagnosis code for fracture of the wrist. If a patient is treated for two successive wrist fractures, the ICD–9–CM code does not provide enough detail to determine if the second fracture is a repeat fracture of the same wrist, a fracture of the other wrist, incorrect billing for delayed healing, or non-union or mal-union of the original fracture.
- ICD–9–CM contains a single procedure code that describes the endovascular repair or occlusion of head and neck vessels (39.72). It does not describe the artery or vein on which the repair is performed, the precise nature of the repair, or whether the approach is a percutaneous procedure or is transluminal with a catheter.
- Four or more ICD–9–CM procedure codes are needed to delineate a spinal fusion procedure with sufficient detail to describe the level of the spine and the devices inserted.

4. Mortality Reporting and Biosurveillance

The ICD–9 diagnosis code set is no longer supported or maintained by the WHO. As of October 2002, 138 countries have adopted ICD–10 for coding and reporting mortality data, and 99 countries have adopted ICD–10 or a clinical modification for coding and reporting morbidity data. In 1999, the United States adopted ICD–10, but only for mortality reporting. Until the United States implements ICD–10 for morbidity reporting applications, data incomparability will continue to increase throughout the world.

As we become a global community, it is vital that our health care data represent current medical conditions and technologies, and that they are compatible with the international version of ICD–10. Because the United States is capturing morbidity data using the outdated ICD–9–CM, there are problems identifying new health threats such as anthrax, Severe Acute Respiratory Syndrome (SARS), and Monkeypox.

The lack of specificity in ICD–9–CM also limits our ability to develop rapid interventions for emerging diseases affecting international populations. Diagnosis and procedure information are captured from administrative data that are submitted on health care claims, and admission and discharge summaries, but if the codes do not match the international standard and are unable to be compared, their significance is lost. Additionally, hospitals utilize diagnosis and procedure codes for utilization review, disease management, and research. Therefore, in addition to the need for precise diagnosis and procedure codes for payment purposes, detail and precision in coding are critical to the national and international health care community for mortality reporting, biosurveillance, treatment of patients, hospital management, and research.

IV. ICD–10 and the Development of ICD–10–CM and PCS

A. Overview

The WHO developed ICD–10 in 1989, and it was adopted by the World Health Assembly in 1990. Currently, the United States is the only G7 nation (the other G7 nations are Canada, France, Germany, Great Britain, Italy and Japan) continuing to use ICD–9 for morbidity reporting. Furthermore, Great Britain, Denmark, Finland, Iceland, Norway, Sweden, France, Australia, Belgium, Germany, and Canada use a clinical modification of ICD–10 for reimbursement and/or administrative purposes.

ICD–10–CM and ICD–10–PCS provide specific diagnosis and treatment information that can improve quality measurements and patient safety, and the evaluation of medical processes and outcomes. ICD–10–PCS has the capability to readily expand and capture new procedures and technologies.

For quality improvement programs to effectively result in meaningful clinical outcomes, improved practice management processes that document and measure patient care, and sustain provider investment in services that improve quality of care, the ability to modify or add to a list of treatments, diseases and conditions is essential. The ICD–10 code sets provide a standard coding convention that is flexible, providing unique codes for all substantially different procedures or health conditions and allowing new procedures and diagnoses to be easily incorporated as new codes for both existing and future clinical protocols.

B. ICD–10–CM Diagnosis Codes

The NCHS has developed a clinical modification of the WHO's ICD–10 called ICD–10–CM for reporting diagnosis codes. As in the relationship between ICD–9 and ICD–9–CM Volumes 1 and 2, ICD–10–CM codes can be mapped back to the ICD–10 codes. The NCHS has worked closely with specialty societies to ensure clinical utility and input into the process of creating the clinical modification, with comments from a number of prominent specialty groups and organizations that addressed specific concerns or perceived unmet clinical needs encountered with ICD–9–CM. The NCHS also had discussions with other users of the classification, specifically nursing, rehabilitation, primary care providers, the National Committee for Quality Assurance (NCQA), long-term care and home health care providers, and managed care organizations to solicit their comments about the classification.

ICD–10–CM diagnosis codes are three to seven alphanumeric characters; the number of ICD–10–CM codes is approximately 68,000. The ICD–10–CM code set provides much more information and detail within the codes than ICD–9–CM, facilitating timely electronic processing of claims by reducing requests for additional information.

ICD–10–CM also includes the following improvements over ICD–9–CM:

- Significant improvements in coding primary care encounters, external causes of injury, mental disorders, neoplasms, and preventive health.
- Advances in medicine and medical technology that have occurred since the last revision.
- Codes with more detail on socioeconomic, family relationships, ambulatory care conditions, problems related to lifestyle, and the results of screening tests.
- More space to accommodate future expansions (alphanumeric structure).
- New categories for post-procedural disorders.
- The addition of laterality—specifying which organ or part of the body is involved when the location could be on the right, the left, or could be bilateral.
- Expanded distinctions for ambulatory and managed care encounters.

ICD–10–CM codes with the same first three digits have common traits, and each additional digit adds more specificity. For example:

I49. Other cardiac arrhythmias
I49.0 Ventricular fibrillation and flutter
I49.01 Ventricular fibrillation
I49.02 Ventricular flutter

Post-procedural disorders specific to a particular body system are located in categories created at the end of each chapter. Diseases are arranged according to an axis of classification based on etiology, anatomy, or severity, with anatomy being the primary axis for ICD–10–CM. (See section V of this proposed rule for a chart that compares ICD–9–CM, ICD–10–CM, and ICD–10–PCS codes).

C. ICD–10–PCS Procedure Codes

CMS developed a procedure coding system, ICD–10–PCS. ICD–10–PCS has no relationship to the basic ICD–10 diagnostic classification, which does not include procedures, and has a totally different structure from ICD–10–CM. ICD–10–PCS is sufficiently detailed to describe complex medical procedures. This becomes increasingly important when assessing and tracking the quality of medical processes and outcomes, and compiling statistics that are valuable tools for research. ICD–10–PCS has unique, precise codes to differentiate body parts, surgical approaches, and devices used. It can be used to identify resource consumption differences and outcomes for different procedures, and describes precisely what is done to the patient.

ICD–10–PCS codes have seven alphanumeric characters and group together services into approximately 30 procedures identified by a leading alpha character. There are 16 sections of tables that determine code selection, with each character having a specific meaning. The first character shows the type of procedure by clinical specialty. Nearly half of these 16 sections remain undesignated at this time, leaving room for future expansion. Each subsequent place in the code has a specific function, the meaning of which may change depending on the section. For example, the fifth character in the imaging section identifies the contrast material used, while the fifth character in the medical and surgical section identifies the surgical approach. The second character defines the body system with the exception of the rehabilitation and mental health sections, in which the second character defines the type of procedure performed.

Example: the Medical and Surgical Section is organized as follows:

CHARACTERS

1	2	3	4	5	6	7
Name of Section	Body System	Root Operation	Body Part	Approach	Device	Qualifier

D. Statutory Requirements for Adoption of ICD–10–CM and ICD–10–PCS

Under sections 1172(b), (c), (f), and (g) of the Act, the Secretary must follow certain procedures and pursue certain objectives when adopting a modification to an initial standard. Under section 1172(b) of the Act, any standard adopted by the Secretary must be consistent with the objective of reducing the administrative costs of providing and paying for health care. As discussed in detail in section XI of this proposed rule, we believe that the costs for implementing ICD–10–CM and ICD–10–PCS would be offset by the benefits within four years of implementation.

Under section 1172(c)(1) of the Act, any standard adopted by the Secretary must be a standard that has been developed, adopted or modified by a standard setting organization (SSO). Under section 1172(c)(2)(B) of the Act, however, section 1172(c)(1) does not apply if no SSO has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under HIPAA. To our knowledge, no SSO has developed, adopted, or modified a standard code set that is suitable for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions. Therefore, we are proposing to adopt ICD–10–CM and ICD–10–PCS under section 1172(c)(2)(B) of the Act.

We note that the SNOMED Clinical Terms (CT)® code set may initially appear to be a standard developed by an SSO for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions. The College of American Pathologists (CAP), which developed SNOMED CT®, is accredited by the American National Standards Institute (ANSI) as an

accredited standards developer. The scope of the CAP's accreditation, however, is limited. The CAP is accredited for activity relating to clinical terminology that focuses on standardizing that terminology across the breadth of medicine. Consistent with this scope of focus, SNOMED CT®, which is now supported by the International Health Terminology Standards Development Organization (*http://www.ihtsdo.org*), is clinical terminology that is primarily designed for primary documentation of clinical care. SNOMED CT® is not designed for carrying out health care transactions. In fact, part of the CAP's scope of ANSI accreditation is deriving mapping strategies from clinical reference terminology and medical classification schemes and codes sets used for statistical, billing, or user interface purposes. Thus, in order to be useful for health care transactions, the SNOMED CT® code set would first have to be mapped to a classification coding system, such as ICD–10–CM. (For further discussion of SNOMED CT® and its potential value to the development of electronic health records (EHRs), please refer to section VI of this proposed rule.) For these reasons, we do not believe that SNOMED CT® qualifies under section 1172(c)(1) of the Act as a standard developed by an SSO for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions.

Under section 1172(c)(3) of the Act, the Secretary must consult with the following organizations before adopting a standard that was not developed, adopted, or modified by an SSO:

- The National Uniform Billing Committee (NUBC).
- The National Uniform Claim Committee (NUCC).
- The Workgroup for Electronic Data Interchange (WEDI).
- The American Dental Association (ADA).

These organizations are members of the Designated Standard Maintenance Organization (DSMO) Steering Committee. The DSMO Steering Committee considered a January 8, 2003 DSMO Change Request submitted by the Centers for Disease Control seeking modification to the transaction code set to accommodate ICD–10–CM and ICD–10–PCS. The DSMO Steering Committee approved the change request and recommended the adoption of implementation specifications that would support the implementation of ICD–10–CM and ICD–10–PCS to the NCVHS.

Furthermore, CMS also consulted with WEDI regarding ICD–10–CM and ICD–10–PCS after two industry-focused informational forums they conducted on ICD–10–CM and ICD–10–PCS during 2006. In a letter to the Secretary dated May 31, 2006, WEDI outlined discussions that occurred during an ICD–10–CM and ICD–10–PCS forum on April 19th and 20th 2006 in Chicago that was co-chaired by representatives of the American Hospital Association, and Blue Cross and Blue Shield of South Carolina. The purpose of the forum was to solicit audience discussion and input on various implementation issues surrounding the possible adoption of the ICD–10–CM and ICD–10–PCS code sets. The forum was not intended to debate the issue of whether these code sets should be adopted, but rather what would need to occur if they were adopted. CMS will further consult directly with NUBC, NUCC, and the ADA before adopting any ICD–10 code set as a modification.

Under section 1172(f) of the Act, the Secretary must rely on the recommendations of the NCVHS established under section 306(k) of the Public Health Service Act and must consult with appropriate Federal and State agencies and private organizations.

The Secretary must publish notification in the **Federal Register** of any recommendation of the NCVHS. The NCVHS has conducted 8 days of hearings with providers, health plans, clearinghouses, vendors, and interested stakeholders on the adoption of ICD–10–CM and ICD–10–PCS in place of ICD–9–CM as the HIPAA adopted standard for reporting diagnoses and hospital inpatient services in standard transactions. (A list of organizations that provided comments to the NCVHS is available at *http://www.ncvhs.hhs.gov/031105a3.htm*, accessed 8–12–08.) In a letter dated November 5, 2003, the NCVHS submitted to the Secretary its recommendation to adopt ICD–10–CM and ICD–10–PCS. This letter is available at *http://www.ncvhs.hhs.gov/031105lt.htm*, accessed 8–12–08. The Secretary also has considered input from Federal and State agencies and private organizations regarding the adoption and implementation of ICD–10–CM and ICD–10–PCS, and has received input from a number of professional organizations and other industry stakeholders. The following organizations representing providers, health plans, clearinghouses, and vendors are among the stakeholders that have provided input:

- The American Health Information Management Association (AHIMA).
- The American Medical Association (AMA).
- The Blue Cross Blue Shield Association (BCBSA).
- The Medical Group Management Association (MGMA).
- Health Information and Management Systems Society (HIMSS).
- America's Health Insurance Plans (AHIP).

V. Comparison of ICD–9–CM Versus ICD–10–CM and ICD–10–PCS

COMPARISON

ICD–9–CM diagnosis codes	ICD–10–CM diagnosis codes
3–5 characters in length	3–7 characters in length.
Approximately 13,000 codes.	Approximately 68,000 available codes.
First digit may be alpha (E or V) or numeric; Digits 2–5 are numeric	Digit 1 is alpha; Digits 2 and 3 are numeric; Digits 4–7 are alpha or numeric.
Limited space for adding new codes	Flexible for adding new codes.
Lacks detail	Very specific.
Lacks laterality	Has laterality.
Difficult to analyze data due to non-specific codes	Specificity improves coding accuracy and richness of data for analysis.
Codes are non-specific and do not adequately define diagnoses needed for medical research.	Detail improves the accuracy of data used for medical research.
Does not support interoperability because it is not used by other countries.	Supports interoperability and the exchange of health data between other countries and the U.S.

COMPARISON—Continued

ICD–9–CM procedure codes	ICD–10–PCS procedure codes
3–4 numbers in length	7 alpha-numeric characters in length.
Approximately 3,000 codes	Approximately 87,000 available codes.
Based upon outdated technology	Reflects current usage of medical terminology and devices.
Limited space for adding new codes	Flexible for adding new codes.
Lacks detail	Very specific.
Lacks laterality	Has laterality.
Generic terms for body parts	Detailed descriptions for body parts.
Lacks description of methodology and approach for procedures	Provides detailed descriptions of methodology and approach for procedures.
Limits DRG assignment	Allows DRG definitions to better recognize new technologies and devices.
Lacks precision to adequately define procedures	Precisely defines procedures with detail regarding body part, approach, any device used, and qualifying information.

Both ICD–10–CM and ICD–10–PCS provide laterality, precise anatomical descriptions, methods to report the exact causes of injury in diagnosing conditions, and approaches used to perform specific procedures. Laterality refers to the precision with which ICD–10–CM and ICD–10–PCS describe conditions and treatments for the anatomical right and left side. Information comparing ICD–10–CM and ICD–9–CM Volumes 1 and 2 is available at: *http://www.cdc.gov/nchs/about/otheract/icd9/icd10cm.htm* (accessed 8–12–08). Information comparing ICD–10–PCS and ICD–9–CM Volume 3 is available at: *http://www.cms.hhs.gov/icd9providerdiagnosticcodes/08_icd10.ASP* (accessed 8–12–08).

VI. Discussion of SNOMED CT®

SNOMED Clinical Terms® (CT) is a comprehensive clinical terminology that provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms that are unique to particular organizations or localities. It contains over 366,170 concepts with unique meanings and formal logic-based definitions that are organized into hierarchies. Some examples of these hierarchies are:

- Staging and scales—contains concepts naming assessment scales and tumor staging systems.
- Social context—contains social conditions and circumstances significant to health care.
- Observable entity—concepts represent a question or procedure which, when combined with a result, constitute a finding.

In order to express these clinical concepts, SNOMED CT® contains more than 993,420 English language descriptions, and approximately 1.46 million semantic relationships. It would be impractical to attempt to manually assign SNOMED–CT® codes. The number of terms and level of detail in a reference of clinical terminology such as SNOMED CT® cannot be effectively managed without automation, and are not suited for the secondary purposes for which classifications systems such as ICD–10–CM and ICD–10–PCS are used because of their immense size, considerable granularity, complex hierarchies, and lack of reporting rules.[1]

SNOMED CT® is a clinical terminology that is described as an input system that is primarily designed for the primary documentation of clinical care. A clinical terminology intended to support clinical care processes should not be manipulated to meet reimbursement and other external reporting requirements. Such manipulation presents the potential to adversely affect patient care, the development and use of decision support tools, and the practice of evidence-based medicine.

ICD–9–CM, ICD–10–CM, and ICD–10–PCS are classification coding conventions that are typically used for reporting requirements where data aggregation is advantageous. A classification system such as ICD arranges like entities for retrieval. It aggregates granular clinical concepts into categories for secondary data purposes. Examples of current use of this data include:

- Designing health care delivery systems.
- Setting health policy.
- Tracking public health and risks.
- Monitoring resource utilization.
- Processing claims for reimbursement.

The benefits of using SNOMED CT® increase if it is linked to a classification system such as ICD–10–CM and ICD–10–PCS for the purpose of generating health information that is necessary for statistical analysis and reimbursement. The use of both SNOMED–CT® and ICD–10–CM and ICD–10–PCS brings value to the development of interoperable electronic health records (EHR). The linkage of these two different coding systems for multiple purposes is accomplished through mapping.

''Mapping is the process of linking content from one terminology to another or to a classification.'' (*http://library.ahima.org*), accessed 8–12–08. It requires deciding how different terminologies match, are similar, or differ. Mapping provides a link between terminologies to facilitate—

- Use of data collected;
- Retaining the value of data when migrating to newer databases; and
- Avoiding entering data multiple times, and the risk of increased costs and errors.

Using SNOMED CT® mapped to ICD–10–CM and ICD–10–PCS permits the use of a clinical terminology that could be the basis for EHRs and the ICD–10–CM and ICD–10–PCS classification coding system that is used for reporting and data trend analysis.

As discussed in section IV of this proposed rule, we did not consider adopting SNOMED CT® as an alternative for ICD–10–CM and ICD–10–PCS because the code sets are designed for distinctly different purposes. We do not believe that SNOMED CT® qualifies under section 1172(c)(1) of the Act as a standard for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions. For similar reasons, we do not believe that we are required under the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, to consider adopting SNOMED CT®. The NTTAA and Office of Management and

[1] ''Coordination of SNOMED–CT® and ICD–10: Getting the Most out of Electronic Health Record Systems'' Sue Bowman, RHIA, CCS, director of coding policy and compliance, AHIMA; Perspectives in Health Information Management Spring 2005 (May 26, 2005) *http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_027179.html*, accessed 8–12–08.

Budget (OMB) Circular No. A–119, which provides some historical background and interpretation of parts of the NTTAA, directs Federal agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical. Because we do not believe that SNOMED CT® is a suitable standard for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions, we believe that neither the NTTAA nor OMB Circular A–119 requires that we consider it for adoption.

VII. Alternatives To Adopting ICD–10 Code Sets

In deciding to propose adoption of ICD–10–CM and ICD–10–PCS, we considered a number of alternatives. We invite public comment on the following discussion of those alternatives and our rationale:

A. Utilize Unassigned Codes

It would be possible to extend the life of ICD–9–CM by assigning codes to new diagnoses and procedures without regard to the hierarchy of the code set. This hierarchy groups procedures by body systems, and then groups similar procedures that apply to a specific body system into categories. For example, ICD–9–CM Volume 3 was examined to identify any open series of codes that could be used for new procedures and technologies. Codes 17.00–17.99 (located between Chapter 3: Operations on the Eye, and Chapter 4: Operations on the Ear) were not being used. This series of 100 codes could be used for a wide range of new procedures and technologies, adding additional space for expansion within the existing structure of the ICD–9–CM procedure volume. Additionally, codes 00.00—00.99 were not in use. The ICD–9–CM Coordination and Maintenance Committee decided to create a chapter in this unused location. This decision enabled the creation of 100 new codes to identify procedures that could not be assigned a code within the existing, and more appropriate, chapters because of space limitations. CMS departed from the current organizational structure of ICD–9–CM procedures when we created a variety of procedure codes in a new chapter 00, Procedures and Interventions NEC (NEC means *Not Elsewhere Classified*). CMS has created new codes in all 10 categories within chapter 00. Details on CMS coding changes are available on the CMS Web site at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes*, accessed 8–12–08.

While this approach of placing codes in a non-hierarchically-created structure does extend the ability to assign ICD–9–CM codes to new diagnoses and procedures, it does not represent a long-term solution to the code shortage. It will only be an effective solution as long as there are empty code slots. Moreover, it does not address the remaining shortcomings of ICD–9–CM discussed above, such as the critical lack of detail that is required to support evolving business needs, for example, in the areas of biosurveillance and quality monitoring. While there have been space issues in ICD–9–CM Volumes 1 and 2, they have not been as pressing as the space needs in ICD–9–CM Volume 3. New categories/codes have been added within the chapters (body systems) of the classification, but not necessarily within the appropriate section within the chapter. New concepts have been incorporated into the existing structure, and in some instances this has meant not fully representing the concept as proposed because of space limitations. Some issues have been deferred and incorporated into ICD–10–CM because the concepts were inconsistent with the existing structure of ICD–9–CM. Unlike the procedures in ICD–9–CM Volume 3, which is a United States-developed system, the ICD–9–CM diagnosis codes are based on the WHO codes and must be consistent with the established structure.

The disadvantage of this solution is that it destroys the natural hierarchy inherent in the code set. This hierarchy assists a coder or health care professional in choosing the most appropriate code since one can quickly review closely-related codes. Common coding practices do not require searches for unrelated procedures in a separate part of the coding book. However, these new chapters capture a very diverse group of unrelated procedures that affect a variety of body systems and are not logically placed in the chapters to which they relate. This creates considerable confusion for coders and difficulty locating the new codes, raising the likelihood of coding errors and negatively affecting productivity.

B. Use CPT–4 for Coding Hospital Inpatient Procedures

The American Medical Association (AMA) developed and maintains the Physicians' Current Procedural Terminology (CPT) coding system to capture physician services. CPT also has been used to capture services performed in outpatient and ambulatory care settings, and is the HIPAA-adopted standard code set for reporting physician and certain other health care services. While evaluating the need to replace ICD–9–CM, the AMA recommended that CPT be used for coding inpatient services. A letter from the AMA's medical organizations supporting the use of CPT for inpatient coding was sent to the Secretary on September 23, 2002. A copy of this letter is included in the Summary Report of the ICD–9–CM Volume 3 Coordination and Maintenance Committee, December 6, 2002 meeting at *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes* (accessed 8–12–08). The AMA was concerned about industry suggestions that a uniform procedure coding system be identified for use in all health care settings. If this were to be the case, the AMA wanted CPT to be considered as that uniform procedure coding system.

The NCVHS had previously evaluated ICD–9–CM Volume 3 and CPT as potential coding systems that could be used to capture services in all health care settings. After extensive hearings and discussions, the NCVHS issued a ''Report of the National Committee on Vital and Health Statistics Concerning Issues Relating to the Coding and Classification Systems'' in November 1990. It found structural problems and serious flaws with both CPT–4 and ICD–9–CM Volume 3. During 1993, an NCVHS subcommittee held three meetings and three working sessions which addressed the creation of a single procedure classification system for multiple purposes in the United States. It was felt that neither system could capture services in all health care settings. Despite continuing NCVHS hearings, there has been no endorsement of the use of CPT for hospital inpatient procedure coding.

The Government Accountability Office (GAO) undertook a study on the use of multiple procedure coding systems, issuing a final report in August 2002 entitled, ''HIPAA Standards, Dual Code Sets Are Acceptable for Reporting Medical Procedures'' (GAO–02–796). The report concluded that ICD–9–CM Volume 3 and CPT do not meet all of the criteria for standard code sets under HIPAA and the procedural code set requirements recommended by NCVHS, including the criteria for adequate levels of detail for data analysis, and a capacity to add new codes in response to new technology. GAO sought advice from industry experts such as the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) as to whether CPT could be used for inpatient coding. AHA and AHIMA reported that CPT ''does not adequately capture

facility-based, non-physician services.'' The GAO report states that CPT has not been shown to be acceptable or comprehensive enough to serve as a single procedure code set for reporting both hospital inpatient and outpatient physician services. Therefore, GAO did not recommend the use of CPT–4 to capture inpatient services. Additional criticisms of CPT are that it does not include laterality, it has no predictable syntax, and the detail provided is inconsistent across procedures.

The AHA, Federation of American Hospitals, and AdvaMED wrote a letter to the NCHVS on November 19, 2002 regarding the implementation of ICD–10–CM and ICD–10–PCS. The letter endorsed the implementation of ICD–10–CM and ICD–10–PCS as a national standard, and opposed the use of CPT for hospital inpatient services because it was designed for services more commonly provided in physicians' offices, not services provided in a hospital inpatient setting.

C. Wait and Adopt ICD–11

One possible option is to forego adoption of ICD–10 and wait until ICD–11 is ready for implementation. The WHO, the developer of the ICD classification, has begun preliminary work on ICD–11. However, no firm timeframes for the completion of developmental work or testing have been identified, and no firm implementation date has been designated. Work has not yet begun on developing the companion procedure codes needed to implement ICD–11 in the United States. This means that the earliest projected date for implementation would be 2020, assuming that no clinical modification is needed for the ICD–11 and that the companion procedure code set could be completed in time. We project that we could not implement ICD–11 until 2016 because it is still in development, testing would be required, and there are no firm timeframes for completion of developmental work.

In addition, ICD–11 will follow the same alphanumeric structure as ICD–10, which differs from that of ICD–9. Since ICD–11 would build upon ICD–10, many of the costs and much of the work associated with upgrading to ICD–11 will be mitigated by ICD–10 implementation. This option of waiting for ICD–11 was eliminated because there are no confirmed dates for ICD–11 readiness or adoption, ICD–11 will not include a procedure classification system and without ICD–10 to build upon, use of ICD–11 is likely to take longer to implement. ICD–9–CM would still have to be used in the interim, and ICD–9–CM is not the pathway to ICD–11 because it has a different structure than both ICD–10 and the anticipated ICD–11.

VIII. Provisions of the Proposed Regulation

A. Use of ICD–10–CM and ICD–10–PCS by Covered Entities

In this proposed rule, we propose to adopt the ICD–10–CM and ICD–10–PCS code sets to replace the ICD–9–CM Volumes 1 and 2 code sets for reporting diagnoses and Volume 3 code set for reporting procedures when conducting standard transactions. We would revise § 162.1002(b) and § 162.1002(c), and adopt ICD–10–CM and ICD–10–PCS in place of ICD–9–CM, Volumes 1 and 2, and 3. We would adopt ICD–10–CM to replace ICD–9–CM Volumes 1 and 2, including the official coding guidelines, for coding diseases, injuries, impairments, other health problems and their manifestations, and causes of injury, disease, impairment, or other health problems. Additionally, we would adopt ICD–10–PCS to replace ICD–9–CM Volume 3, including the official coding guidelines, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals: prevention, diagnosis, treatment, and management.

HIPAA covered entities would be required to use these codes when diagnoses and hospital inpatient procedures need to be coded in HIPAA transactions. Because ICD–10–PCS codes are only used for inpatient hospital procedures, the ICD–10–PCS codes would not be used in outpatient transactions.

In arriving at this proposal, we considered myriad input from the public, NCVHS, professional organizations, and others. Our deliberations centered around two sets of issues: the limitations of ICD–9–CM (Volumes 1 and 2, and 3), as discussed above, and the adoption of alternatives to ICD–10–CM and ICD–10–PCS code sets.

We will establish an ICD–10–CM/PCS Coordination and Maintenance Committee. This committee will follow the same procedures currently used by the ICD–9–CM Coordination and Maintenance Committee to consider new codes and revisions to existing codes.

We acknowledge that this proposed rule does not specifically address impacts on prospective payment systems that currently use ICD–9–CM codes. We determined that these issues can best be addressed through the usual IPPS and other proposed rules that impact payment decisions and applications.

B. Effective Dates

The effective date of revised § 162.1002 would be 60 days after a final rule is published in the **Federal Register**.

C. Proposed Compliance Dates

Under section 1175 of the Act, the compliance date of a modification to a HIPAA standard may not be earlier than the 180th day following the effective date of the adoption of the modification. The Secretary may consider the nature and extent of the modification when determining the compliance date. If the Secretary determines an extension is appropriate for small health plans, he may extend the time for their compliance. NCVHS testimony and subsequent industry input clearly indicate that the implementation of ICD–10 will be a significant undertaking. The activities involved in this implementation are discussed in detail in the impact analysis section of this proposed rule.

Many covered entities have stated that they will need at least 2 years from the publication of a final rule to implement ICD–10. Some have argued that 3 years will be needed, noting that the original 2-year implementation period for the initial HIPAA transaction standards proved to be insufficient. Others note that ICD–10 implementation should be viewed in the context of other HIPAA requirements (including the implementation of the National Provider Identifier and the claims attachment transaction standard) and other information technology initiatives, including IT initiatives integral to the Department's transparency activities, and that ICD–10 compliance should not be required until 2012 or later. Coordination with these other health information technology (HIT) initiatives is discussed in the impact analysis of this proposed rule.

HHS and industry health information technology initiatives include interoperability specifications, certification criteria, and standards developed under HIPAA and the Medicare Modernization Act. We describe these initiatives and associated known or projected publication, delivery, or compliance dates below:

- Beginning in September 2006 (and annually thereafter)—Delivery of Healthcare Information Technology Standards Panel (HITSP) interoperability specifications supporting specific use cases.

• May 2007—Compliance date for all covered entities other than small health plans, implementing the HIPAA National Provider Identifier (NPI) in all HIPAA transactions.

• June 2007—Publication of the Certification Commission for Healthcare Information Technology (CCHIT) criteria for certifying inpatient electronic health record products.

• November 2007—Publication of Electronic Prescribing Standards for Medicare Part D Notice of Proposed Rulemaking.

• April 2008—Publication of Final rule regarding standards for Electronic Prescribing under Medicare Part D and adoption of NPI in Electronic Prescribing transactions.

• May 2008—Publication of CCHIT criteria for certifying health information technology networks and systems.

• May 2008—Compliance date for small health plans implementing the HIPAA National Provider Identifier (NPI) in all HIPAA transactions.

• April 2009—Projected compliance date for new e-prescribing standards for the Medicare drug program, and use of NPI in e-prescribing transactions, pursuant to the Medicare Modernization Act. Medicare Part D Sponsors are required to support the standards. Prescribing providers and pharmacies are required to use them only if they choose to engage in e-prescribing.

• 2010—Projected compliance date for the updated retail pharmacy drug claim, which will facilitate processing of Medicare drug claims and affects all pharmacies and plans that process pharmacy claims.

• 2010—Projected compliance date for updated non-pharmacy HIPAA financial and administrative transactions which affects all HIPAA-covered entities. These transactions include the claim, remittance advice, eligibility, and claim status query and response transaction, plan enrollment, and referral authorization. Version 4010/4010A1 of the American Standards Committee X12 group is the currently adopted standard. Version 4010/4010A1 transactions cannot accommodate the larger size of ICD–10 code set; therefore, the new version, 5010, must be implemented in order to implement ICD–10 code sets. Industry representatives have recommended that the compliance date for these standards be at least 18 months before the compliance date for ICD–10 to allow for needed testing and to reduce risk. CMS is currently working on regulatory action regarding the transition to 5010 in order to accommodate the ICD–10 code set.

• 2011—Projected compliance date for the new HIPAA standard for the claims attachment transaction, which would affect all HIPAA-covered entities that are not health plans. This standard addresses the communication of additional information, often of a clinical nature, that may be needed in order to adjudicate a claim.

• 2012—Projected compliance date for small health plans conducting HIPAA claims attachment transactions.

We acknowledge that implementing ICD–10 code sets will require significant effort on the part of covered entities and their vendors. We also recognize the need to transition to a new code set before ICD–9–CM becomes unworkable. Moreover, the enhanced functionality that ICD–10–CM and ICD–10–PCS code sets bring to quality assessment, research, and biosurveillance argue for an earlier implementation. We have weighed all these factors in arriving at our proposal.

We propose October 1, 2011 as the compliance date for ICD–10–CM and ICD–10–PCS code sets for all covered entities. It is important to note that the compliance date must occur on October 1 in order to coincide with the effective date of annual Medicare inpatient PPS updates. We believe that a 2011 compliance date permits adequate time for covered entities and their vendors to complete the necessary implementation activities. As shown above, our projected compliance dates for other health IT initiatives have been sequenced in a manner that will allow covered entities to concentrate their efforts on ICD–10 implementation (including the implementation of the 5010 transactions) during the relevant period.

CMS believes it is in the industry's best interest (including small health plans) to have a single compliance date for ICD–10–CM and ICD–10–PCS. This will reduce burden on both providers and insurers who will be able to edit on a single new coding system for claims received for encounters and discharges occurring on or after October 1, 2011. The proposed compliance date, we believe, is also sufficiently far in the future to provide all sectors of the industry, including small health plans, adequate time to implement the code sets. A single compliance date also will significantly reduce confusion in processing claims and analyzing data. Historically, all previous versions of the ICD coding systems, such as ICD–7 and ICD–8, have been implemented on a single date. The health care industry has come to expect this consistent approach to updating ICD coding systems. To allow two different compliance dates would create problems for all sectors of the health care industry. Examples of problems that would arise if both ICD–9–CM and ICD–10 codes were allowed to be reported for the same date of service include:

• Increased errors—ICD–9–CM and ICD–10–CM have codes that can include the same number of digits and similar codes. Allowing both code systems to be used and reported will create confusion in processing and interpreting coded data. Claims may be denied for services if the edits are established for ICD–10–CM codes, but ICD–9–CM codes are reported. Claims may be returned as errors if edits indicate there are too many or too few digits, when in fact a different coding system is being used.

• Provider burden—Maintaining both ICD–9–CM and ICD–10–CM will place a significant burden on providers. Providers would have to maintain both coding systems for a year because of different reporting requirements by some payers or entities if there were two implementation dates. This will not only increase burden, but would also lead to additional error messages and returned claims if the provider does not select the required coding system when claims are coded. Coders would be burdened by having to recall and apply codes from different coding systems for a year. It is much easier to simply learn and move to the new coding system for encounters occurring on a single fixed date.

• Systems problems—if providers, insurers, and other entities are required to report and accept both coding systems for encounters occurring during a year, there would be significant system implications in trying to determine which coding system was being used to report the coded data. As indicated above, this may lead to denied and returned claims.

• Payment update challenges—coded data are used to update payment systems such as the inpatient prospective payment system. If codes are reported in both ICD–9–CM and ICD–10–CM during a given year, it will be difficult to assess the need to update and refine the payment system based on coded data.

• Problems with national health care data—by allowing the use and reporting of two different payment systems, the national data will be difficult to analyze and interpret. This not only creates problems with updating payment systems, as indicated above, but also creates problems in interpreting trend data on health care conditions. It will be problematic to make national projections on quality of care and outcomes when two different coding

systems are used for encounters during the same time period. This is further amplified when single providers report with two different coding systems to small entities, but with ICD–10 to large entities. Comparing national data and assessing outcomes will be challenging.

We solicit public comment on the proposed compliance date of October 1, 2011.

We anticipate that upon publication of this proposed rule in the **Federal Register**, both the industry and CMS will actively initiate and/or complete planning for implementation of ICD–10. While not included under the auspices of this proposed rule, we also acknowledge the impact of the implementation of the ASC X12 Technical Reports Type 3, Version 005010, hereinafter referred to as Version 5010, on ICD–10 implementation timelines. Once the ICD–10 and Version 5010/NCPDP Version D.0 final rules are published, we estimate that both CMS and the industry will begin documenting the requirements for both ICD–10 and Version 5010 system changes, initiate and/or complete any gap analyses, and then undertake design and system changes, with Version 5010 progressing first, based on the need to have it in place prior to ICD–10 implementation to accommodate the increase in the size of the fields for the ICD–10 code sets. In the case of Version 5010, system building and testing could commence approximately 12 months prior to a Version 5010 compliance date. We anticipate that ICD–10 external testing could start approximately 15 months prior to the October 2011 compliance date.

Upon publication of these proposed rules for both ICD–10 and Versions 5010/D.0 in the **Federal Register**, the Department, through CMS, plans on proactively conducting outreach and education activities, as well as engaging industry leaders and other stakeholder organizations to provide education and other resources to their respective constituencies. These activities would include roundtable conference calls with the industry, including Medicare contractors, fiscal intermediaries and carriers; hospitals; physicians; other providers; and other stakeholders.

CMS will also develop and make available ''Frequently Asked Questions'' documents, fact sheets, and other supporting education and outreach materials for partner dissemination. Other potential activities will be identified and developed based on stakeholder input. The draft proposed timeline shown below is for preliminary planning purposes, and represents our best estimate, given our current knowledge, of what an implementation timetable might look like. It is subject to revision as updated information becomes available. We solicit industry and other stakeholder comments on our timeline assumptions and our proposed education and outreach strategy.

Draft Proposed Timeline for ICD-10 and Versions 5010/D.0 Implementation

ICD-10	Versions 5010/D.0
8/08 Publish Proposed Rule	**8/08** Publish Proposed Rule
	9/08 Industry begins requirements documentation for systems changes; CMS and industry initiate education and outreach
12/08 CMS/industry begin ongoing education and outreach	
	4/09 Industry build and test systems changes (internal and external testing)
6/09 Industry begin design documentation	
12/09 Industry builds and internally tests systems changes	
	4/10 Compliance date for all covered entities
7/10 – 10/11 Conduct external testing	
10/11 Compliance date for all covered entities	

IX. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 through 3520).

X. Response to Comments

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

XI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354) (as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104–121), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258 and Executive Order 13422, which modifies the list of criteria used for regulatory review) 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 consider this proposed rule to be a major rule, as it will have an impact of over $100 million on the economy. The RIA section of this proposed rule explains our calculations for costs and benefits. We attempt to provide information for the impact analysis, focusing on savings projections and cost estimates. Tables 13 and 14 summarize cost benefit projections. We solicit comments on these data during the comment period for this proposed rule. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess the anticipated costs and benefits before issuing any rule whose mandate requires spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector. That threshold level is currently approximately $130 million. Based on our analysis, we anticipate that the private sector would incur costs exceeding $130 million per year in the first 2 years following publication of the final rule. Our analysis indicates that States would not experience costs exceeding $130 million.

The anticipated benefits and costs of these proposed modifications to the medical data code sets, and other issues raised in section 202 of the UMRA, are addressed later in this document. In addition, under section 205 of the UMRA (2 U.S.C. 1535), having considered at least three alternatives that are referenced in the RIA section of this proposed rule, HHS has concluded that the provisions in this proposed rule are the most cost-effective alternative for implementing HHS' statutory objective of administrative simplification.

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. Executive Order 13132 requires the opportunity for meaningful and timely input by State and local officials in the development of rules that have Federalism implications. The Department consulted with appropriate State and Federal agencies, including tribal authorities and Native American groups, as well as private organizations. These private organizations included WEDI and the Designated Standard Maintenance Organization (DSMO) coordinating committee according to section 1178(c)(3) of the Social Security Act.

In order to validate the fiscal and operational impact of this rule on State Medicaid agencies, current data on costs for States to implement a new code set would be necessary. We reference in the RIA of this proposed rule industry studies that were conducted and that may provide some insight into this information for States. In addition, during the comment period, we hope that State Medicaid agencies will provide any additional and/or updated information.

The Department has examined the effects of provisions in this proposed rule as well as the opportunities for input by the States to the proposed rule. The Federalism implications of the proposed rule are consistent with the provisions of the Administrative Simplification subtitle of HIPAA by which the Department is required by the Congress to promulgate standards for the interchange of certain health care information via electronic means. Under section 1178(a)(1) of the Act, these standards preempt contrary State law.

The States are invited to comment on this section and all sections of this proposed rule. The Department concludes that the policy in this proposed rule has been assessed in accordance with the principles, criteria, and requirements in Executive Order 13132; that this proposed rule is not inconsistent with that Order; that this proposed rule would not impose significant additional costs and burdens on the States; and that this proposed rule would not affect the ability of the States to discharge traditional State governmental functions.

1. Regulatory Flexibility Act—Impact on Small Businesses

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by qualifying as small businesses under the Small Business Administration's (SBA's) size standards (revenues of $6.5 million to $31.5 million in any 1 year). For details, see the SBA's Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf* (refer to Sector 62) (accessed 8–12–08).

We discuss the impact of the proposed rule on small entities in section XI.D of this document.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. (See the discussion at section XI.D for our discussion of the expected impact on small rural hospitals.)

B. Anticipated Effects

1. Objective

The objective of this regulatory impact analysis is to summarize the costs and benefits of moving from ICD–9–CM to ICD–10–CM and ICD–10–PCS code sets in the context of the current health care environment.

The following are the three key issues that we believe necessitate the need to update from ICD–9–CM to ICD–10–CM and ICD–10–PCS:

- ICD–9–CM is out of date and running out of space for new codes.
- ICD–10 is the international standard to report and monitor diseases and mortality, making it important for the U.S. to adopt ICD–10 classifications for reporting and surveillance.
- ICD codes are core elements of many HIT systems, making the conversion to ICD–10 necessary to fully realize benefits of HIT adoption.

For a more detailed discussion of the limitations of ICD–9–CM, please refer to section III.B in the preamble of this proposed rule. No other viable alternatives to adopting ICD–10 were identified. The costs and benefits for moving from ICD–9–CM to ICD–10–CM and ICD–10–PCS were assessed within the requirements of the Executive Orders and Acts cited in section XI.B of this regulatory impact analysis.

2. Background

Two major papers analyzed the costs and benefits of adopting the ICD–10 codes: (1) a March 2004 RAND study, *http://www.rand.org/pubs/technical_reports/2004/RAND_TR132.pdf* (accessed 8–12–08) and (2) an October 2003 study by the Robert E. Nolan Company commissioned by the Blue Cross and Blue Shield Association, *http://www.renolan.com/healthcare/icd10study_1003.pdf* (accessed 8–12–08). Both studies agreed that the basic elements driving the cost of implementing the ICD–10 code sets were training, productivity losses, and system changes. Table 6 summarizes the differences in cost and benefit estimates between the two studies.

In considering the studies, HHS evaluated both on the basis of the following criteria:

- The depth and completeness of the analysis and supporting evidence for the conclusions;
- Data sources and a presentation of the data limitations;
- The perceived objectivity of the analysis as demonstrated by the discussion of data sources and the rigor of the analysis;
- The point of view the analysis adopted—whether from the general societal perspective or from a specific point of view (for example, from the payer or provider view point); and
- HHS' ability to explain and justify in a Regulatory Impact Statement the findings and conclusions presented in each of the studies.

a. Nolan and RAND Studies: Analysis and Limitations

ICD–10 code sets would likely represent the most complex of all the HIPAA code sets. Also, because the ICD–9–CM code set is used for reporting diagnoses, adoption of the new codes will likely touch every provider who submits diagnostic codes, and every payer that processes health care claims. Given the lack of quantifiable data, both studies were compelled to make numerous assumptions as to the possible behavioral changes resulting from the new codes. The key differences are how each study justifies its assumptions and seeks to provide detailed and plausible scenarios.

As the Nolan and RAND reports were the only studies available at the time that outlined the costs and benefits for transitioning from ICD–9 to ICD–10, we employ them for purposes of this impact analysis along with their associated assumptions and limitations. We later discuss HHS' analysis based on our selected model. Overall, NOLAN estimates that it will cost providers and payers between $5.5 billion and $13.5 billion to implement ICD–10–CM and PCS code sets. In addition, Nolan expects there to be an additional $150 million to $380 million in lost productivity.

i. Training

Nolan expects the following number of individuals would require training on the new codes:

TABLE 1—NOLAN STUDY—TRAINING ESTIMATES

*Category	Number of staff	Hours	Training cost in millions $ (including follow-up)
Full-time coders	142,170	24–40	94–141
Physicians/practitioners	754,636	4–12	332–499
Part-time coders and other clinicians	1,455,015	4–40	456–684
Other hospital	44,207	4–40	30–45
Payer plans	117,020	4–80	54–80

*Nolan adapted from chart 6 on page 17.

The Nolan study estimates that 142,170 coders would need training at a cost of $94 million to $141 million. But the study does not differentiate between hospital-based coders and those working in physician offices and clinics. In addition, Nolan identifies another set of 44,207 coders as ''other hospital'' coders, but there is no explanation as to which hospitals are included under this category versus ''full-time coders,'' nor does the Nolan study document the sources of its numbers. According to the American Health Information Management Association Web site (*http://www.ahima.org*, accessed 8–12–08), there are more than 51,000 AHIMA members. As AHIMA is the leading professional association representing specially educated and certified health information management professionals throughout the healthcare industry, we assume, as does the RAND study, that this represents the majority of the number of full-time coders employed in hospitals. Without supporting documentation, we cannot accept Nolan's estimate of 142,000 full-time coders.

The Nolan study estimates that 754,000 physicians would require between 4 to 12 hours of training at a cost of $332 million to $500 million, or $440 to $663 per physician. Given the wide use of ''super-bills'' (forms with codes for diagnosis and procedure codes with their descriptions that are most frequently used by physician practices, and that may or may not include specific charges) to document encounters in office-based practices,

and familiarity with the few codes for which they routinely bill, it seems unlikely that most physicians would require or desire training on the new code sets. We believe that only some physicians would have an interest in learning the new system. Also, it seems likely that large practices would have sufficient need to hire either a part-time or full-time coder. In comparison, RAND estimates that only one out of ten (45,000) physicians would want up to 8 hours of training, and these would most likely be emergency room physicians and surgeons. For these reasons, we believe the RAND numbers more accurately reflect the number of physicians likely to seek training.

Nolan predicts that some 1.5 million clinicians, including nurses and physician assistants, would seek training in the ICD–10 codes at a cost ranging between $313 and $470 per clinician. As in the case of physician training, the Nolan study does not present any explanation for why over a million nurses and physician assistants would want or require training. In some offices, clinicians may perform coding along with their clinical duties, but in most cases, we again expect that superbills or similar forms would be used which require minimal knowledge of the coding structure. On this basis, we rejected Nolan's estimates of clinician training.

Training would be necessary for insurance and health plans that make payments to providers based on the submitted codes. The Nolan study estimates that 117,000 coders working for health plans would require between 4 to 80 hours of training at a cost of between $54 million to $80 million. In this regard, both studies are close on their estimate of the number of personnel and time required for training, with RAND estimating 150,000 personnel requiring 4 to 8 hours of retraining.[2] However, the Nolan study is rather opaque in providing evidence or rationale for its conclusions.

ii. Productivity Losses

The Nolan study distinguishes between short-term (6 months to a year) and permanent productivity loss.

TABLE 2—SHORT-TERM PRODUCTIVITY LOSS

Payer and provider productivity losses resulting from claims rework	$300–600 (million) in first year.
Coder productivity loss for first 3 months	$300–440 (million).

Nolan, adapted from Chart 8, page 20.

TABLE 3—LONG-TERM PRODUCTIVITY LOSS

Coder productivity loss resulting from the greater number of codes and more complex coding structure	$152–380 million.

Nolan, adapted from Chart 9, page 21.

The Nolan study concludes that the extra time ICD–10 requires for coding is largely the result of initial unfamiliarity with the code structure and terminology. However, because of the intrinsic greater complexity of coding and vastly greater number of codes, Nolan assumes there would be a permanent loss of productivity of $152 million to $380 million.

The American Health Information Management Association (AHIMA) and the American Hospital Association (AHA) conducted a field test of the ICD–10–CM codes and issued their report in September 2003. The full report is available at *http://www.AHIMA.org.* The study imposed certain limitations that may have contributed to the extended times in using the new code system (the principal limitation being the absence of digital documents which would enable faster searching for codes).[3] However, overall, the study found that with adequate training and proper coding tools, there should be no loss in coder productivity in the long-run (AHIMA/AHA study, page 25).

Nolan also cites Canadian sources who reported productivity losses during the first 6 months after ICD–10 was implemented, but according to its source, production rebounded to pre-ICD–10 levels.[4]

iii. System Changes

Nolan's analysis of the cost to make system changes rests largely on statements made by various executives who cited the costs of preparing for Y2K and HIPAA. The Nolan study analysis consisted of adjusting those figures for factors such as avoiding hardware purchases, or the inclusion of security and privacy costs in the HIPAA estimates. Nolan estimates the system changes based on an aggregate number that includes privacy and security, and then backs out the cost for implementing the code portion of the costs, concluding that 50 to 70 percent of the costs would be attributable to code changes.[5] However, there is no explanation for how Nolan determined this number. The following table summarizes Nolan's estimates for the cost of implementing system changes in the various affected health care sectors. The estimates are drawn from tables in the Nolan report.

TABLE 4—NOLAN STUDY ESTIMATES OF SYSTEM CHANGES COSTS ACROSS HEALTH CARE SECTORS

	In billions
Facilities and physician offices	$2.6–$8.2
Health plans and insurers	0.4–1.0
Medicaid/Medicare	0.7–1.4

Nolan report, pages 8, 9, 11, 24.

In estimating the costs of the system changes, Nolan compared the implementation of the codes sets to the implementation of the HIPAA sets and broke down the activities into the following tasks:

[2] RAND page 10.

[3] ''ICD–10–CM Field Testing Project'' AHIMA/AHA; September 2003 (*http://www.ahima.org/icd10/documents/FinalStudy_000.pdf*), accessed 8–12–08 page 11; ICD–10 not available in electronic format.

[4] Nolan, page 21.

[5] Nolan, page 6.

TABLE 5—NOLAN STUDY ESTIMATES OF SYSTEM CHANGES COST BY TASK

Project steps	Sub-steps	FTEs	HIPAA	FTEs	ICD–10
* Team Formation and Analysis	Assign project leader	0.25–1.0	$25–$70,000	0.25–1.0	$25–$70,000
	Assemble project team and develop plan.	0.5–2.0	50–140,000	0.5–4.0	50–280,000
	Perform gap and systems analysis ..	0.25	5–25,000	0.5–3.0	50–210,000

* Nolan, page 5, chart 2.

HIPAA required a number of system changes and adoption of a number of new code sets. In the final HIPAA transaction rule, we estimated the cost to implement the Administrative Simplification provisions to be approximately $7.1 billion (65 FR 50356).

Nolan estimates that system changes in hospitals would cost between $2 billion and $6 billion, and $645 million to $2.2 billion for implementing the ICD–10 codes in physician and group practice offices. Nolan, however, does not take into account that hospitals would need to implement both ICD–10–CM and ICD–10–PCS, whereas physician and group practice offices will only need to implement ICD–10–CM. Payers would incur $400 million to $1 billion in costs to implement the ICD–10 code sets. The total cost of $3.045 billion to $9 billion represents from 43 to 127 percent, respectively, of the $7.1 billion estimated for implementing the HIPAA provisions for both provider and plan costs. In addition, the Nolan study separately identifies the system change costs for government programs, including Medicaid and Medicare, at between $700 million and $1.4 billion.[6] In analyzing the cost of implementing ICD–10 code sets for Medicaid State plans, Nolan cites several sources that refer to the costs of modifying the Medicaid Management Information Systems (MMIS), which may require some modifications to accept payments based on the new codes.

Nolan did not estimate any quantitative benefit which is a serious shortcoming of the study, given the Office of Management and Budget's (OMB's) guidance on preparing cost/benefit analyses for major rules.

Based on the studies' designs, it appears that the RAND and Nolan reports had different target audiences; therefore, their respective methodologies differed. RAND considered costs and benefits from the perspective of the general public, while the Nolan study focused on major health care sectors. A key result of this difference is that potential winners and losers in each health care sector are not clearly highlighted in the RAND report.

RAND's methodology is more analytical than Nolan's methodology, albeit there are still limitations to the RAND report. Both RAND and Nolan express the uncertainty in their estimates through presenting ranges for their estimates. RAND, however, provides more detailed scenarios and offers a qualitative analysis of the uncertainty in the variables it uses in its scenarios. Nolan does not offer any explanation for its ranges. Both studies conducted extensive literature reviews.

In conducting the cost and benefit analysis, both reports dissected the estimates into a one-time cost and one-time and recurring benefits in the RAND study. In both the Nolan and RAND studies, nursing homes, clinical labs, Durable Medical Equipment suppliers (DMEPOS), third party administrators, clearinghouses, and small/medium insurers were excluded from their analysis. Table 6 below provides a high-level comparison between the RAND and Nolan studies.

Although RAND does not explicitly break down its analysis beyond the broad categories of ''payer'', ''hospital'', ''physician'', for costs of coding, productivity losses, returned and improper claims, by examining the costs of the generic categories of training, administration, and claims processing, RAND's approach cuts across the subcategories of providers and payers. Only in the analysis of system change costs is there a defect in RAND's method. From the documentation provided, RAND conducted interviews with executives of health care systems of various sizes as measured by membership.[7] It is not clear, however, the span of the interviewed health systems in terms of the types of providers. Without more details, we cannot conclusively determine the extent of the system conversion costs of long-term care facilities, home care providers and other non-hospital organizations. It may be that the system conversion costs for these types of health providers are underrepresented. Similarly, it is not clear how far-ranging is RAND's examination of the various types of payer organizations. It is possible that third party administrators, clearinghouses, and small health plans may be underrepresented in the analysis.

TABLE 6—COMPARISON OF COST AND BENEFIT ESTIMATES IN RAND AND NOLAN STUDIES

[In $ millions]

	RAND	Nolan	Difference	Comments
Costs Training:				
One-time	$200–450	$950–1,500	$750–1,050	• 35 to 50 percent difference attributable to the assumption of part-time coders: RAND assumed 200,00 compared to 1.5 million in the Nolan report. • 25 to 40 percent difference attributable to the number of physicians: RAND assumed 1:10 physicians would be trained compared to most physicians in the Nolan report.
Productivity Losses:				
One-time	50–350	600–1,040	550–690	• The Nolan report treated re-work and short-term losses separate from productivity losses—which may account for the Nolan Report figures.

[6] Nolan, page 7.

[7] RAND, pages 15–16 and Appendix B.

TABLE 6—COMPARISON OF COST AND BENEFIT ESTIMATES IN RAND AND NOLAN STUDIES—Continued

[In $ millions]

	RAND	Nolan	Difference	Comments
Recurring	0–30	152–380	152–350	
System Changes:				
One-time	225–700	3,700–10,600	3,475–9,900	• The Nolan report compared ICD–10 code set implementation to other large scale system changes such as Y2K and HIPAA.
Contract Negotiations	0	82–416	82–416	
Benefits: (in millions)				
More accurate payments for new procedures.	100–1,200	(1)		• The Nolan report claims that vast majority of benefits cannot be achieved without a standard clinical vocabulary. Also, the report states that the benefits asserted by proponents are uncertain and unproven based on literature reviews.
Fewer rejected claims	200–2,500	(1)		
Fewer fraudulent claims	100–1,000	(1)		
Better understanding of new procedures.	100–1,500	(1)		
Improved disease management.	200–1,500	(1)		

[1] Uncertain.

Finally, Nolan also argues that implementing ICD–10 codes would lead to increased incidences of fraud and abuse in its introductory period. We agree with this view since we anticipate that people may take advantage of the initial ambiguity of the new codes, but we also believe that the greater precision of the coding requirements would eventually lead to lower incidences of abuse.

Both studies presented valuable input and relevant information, but based on questions regarding the methods and assumptions presented in each report, we believe that neither should be used as the sole basis for an ICD–10–CM and ICD–10–PCS impact analysis. To address these shortcomings, HHS convened a workgroup to develop a framework consistent with OMB's requirements for an impact analysis. The framework extracted relevant points from both the RAND and Nolan studies, and also identified new internal and external data sources.

Also taken under consideration for purposes of this impact analysis, is a report authored by the Hay Group, Inc., ''Examining the Cost of Implementing ICD–10'', commissioned by America's Health Insurance Plans (AHIP) (hereinafter referred to as the AHIP report'') in October 2006. [8] This report, a white paper based on the previously-referenced RAND and Nolan reports on ICD–10 implementation, is intended to identify the primary sources of ICD–10 implementation costs. It includes a review of existing cost estimates from RAND and Nolan and uses those estimates to develop preliminary estimates of the likely cost to the U.S. health system as a whole. Its scope includes health care providers, private payers, and government payers. The types of costs considered are systems implementation, training, and provider contract renegotiations. Only direct implementation costs are considered. The report does not include the cost of work that must be re-done due to error rates or other forms of lost productivity.

For purposes of this regulatory impact analysis, we used the AHIP report as a litmus test in that it was authored a full 2 years after the RAND and Nolan reports, and held the potential for providing more updated cost estimates. However, it again relies on RAND and Nolan data, and notes that its cost estimates would still have to be adjusted for inflation, which we have already done for this impact analysis. The AHIP report also lacks discussion regarding the monetary benefits that would occur once ICD–10 is implemented. It also does not specifically reference how their estimates were calculated or the sources for many of their assumptions.

We agree with selected segments of the AHIP report, namely its conclusion that implementation of ICD–10 for Medicare and Medicaid would run between $250 and $370 million; we estimate an average of $315 million. Where our analysis and the AHIP report differ is in the cost for the training of physicians on the ICD–10 codes sets, and in the cost of re-negotiating contracts. In the case of the former, we continue to believe that there will be a minimum number of physicians who will desire such training, leaving it instead to their staff coders, or the use of ''super-bills'' to update their coding information. In the case of the latter, we continue to believe that contract re-negotiation costs are considered for purpose of this analysis to be a cost of doing business, and would take place whether or not the transition to ICD–10 took place. We believe that the level of effort to re-negotiate contracts for the purposes of implementing ICD–10 would not be significantly different from other policy-related changes requiring contract renegotiations. We also do not account for AHIP's increase in system implementation costs of between $115 to $416 million due to an accelerated implementation of the ICD–10 code sets versus an orderly, staged rollout as we have proposed.

3. Framework for Impact Analysis

a. The Impact Analysis Workgroup

HHS created a workgroup from a cross-agency, multidisciplinary team with actuarial, economic and coding subject matter expertise from HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE); Centers for Disease Control (CDC)/ National Center for Health Statistics (NCHS); Centers for Medicare & Medicaid Services (CMS); and the Office of the National Coordinator for Health Information Technology (ONC). The workgroup sought guidance from the Department of Defense (DoD), the Department of Veterans Affairs (VA), and contacts from other countries that have implemented ICD–10, to lead the cost-benefit analysis for transition from

[8] ''Examining the Cost of Implementing ICD–10'' White Paper prepared by Thomas F. Wildsmith, FSA, MAAA of HayGroup, Inc. on behalf of the America's Health Insurance Plans, October 12, 2006. *http://www.ehcca.com/presentations/hithipaa414/3_04_1.pdf.*

ICD–9–CM to ICD–10–CM and ICD–10–PCS. Also, Actuarial Research Corporation (ARC) was hired to help the team evaluate and update the data sources and available information. The team critically reviewed several cost-benefit studies and international experiences with ICD–10 implementation. Data were drawn from the RAND study (sponsored by NCVHS), the Nolan study (sponsored by the Blue Cross Blue Shield Association), the American Health Information Management Association (AHIMA), and CMS.

In 2005, the workgroup began the analysis of the costs and benefits by examining and comparing the RAND and the Nolan studies. While both contain useful information, the requirements for regulatory impact estimates demand a somewhat different framework. The workgroup incorporated the basic results from both studies, as well as the Secretary's vision of health care information technology, and reflected costs and benefits by year based on assumed implementation schedules.

The workgroup's analysis assumes that the implementation of ICD–10 code sets would be coordinated with existing HHS health information technology initiatives, and include the required changes to dependent regulations and standards. HHS health initiatives, such as public health/biosurveillance, disease registries, quality monitoring, utilization review, and pay for performance, could employ either ICD–9–CM or ICD–10–CM and ICD–10–PCS code sets.

Conversion costs from ICD–9–CM to ICD–10 code sets are unavoidable and do not include costs associated with the American Standards Committee (ASC) X12N version 5010 standard. ICD–9–CM is an adopted HIPAA code set and the adopted HIPAA Transaction standard (ANSI ASC X12N version 4010/4010A1) does not support ICD–10–CM and ICD–10–PCS code sets. Also, the CMS IPPS uses ICD–9–CM-based Diagnostic Related Groups (DRGs), and the annual regulatory IPPS update would require conversion to ICD–10-based DRGs. Regulatory and standards changes, including implementation of Version 5010 must occur before, or parallel to, conversion to ICD–10–CM and ICD–10–PCS code sets, with sufficient notice to the industry to reconfigure systems, policies and methodologies. For initiatives in the early stages of development, costs to implement ICD–9–CM now, with conversion to ICD–10 code sets later, could be avoided by direct conversion to ICD–10 code sets concurrently with the initiatives.

The following is a detailed discussion of the workgroup's approach, method, and assumptions underlying its costs/benefit analysis.

First, we present an overview of HHS' approach to estimating the costs and benefits based largely on the RAND study but also drawing from the Nolan study and the AHIMA/AHA study.[9] The second part of this section describes in detail the assumptions and models that RAND developed for its estimates and which were adapted for this analysis.

The workgroup's calculations began with the RAND[10] estimates, incorporating additional information from CMS, and some input from Nolan.[11] For each category for which RAND provided a range of high and low costs, a point estimate was generated. When RAND did not include a specific estimate, HHS' point estimate was based on the midpoint of their high and low estimates. RAND's descriptions and 10-year numbers were used to create a year-by-year spread of both costs and benefits. Modifications were made after reconsideration of the RAND study regarding their calculations. These modifications included the addition of productivity losses for outpatient claims; the separation of costs from the benefits for rejected and improper claims; and reconciliation of what were considered inconsistencies in the RAND study. We selected the computed values from the text of the RAND report rather than relying on the values presented in the tables.

HHS also examined estimates from the Nolan study. Nolan specifically estimated outpatient productivity losses, a cost that RAND did not estimate. For outpatient productivity, the Impact Analysis Work group assumed the short-term impact may be very small in terms of extra time per claim, but because of the large number of claims, the loss was judged to be significant. In its analysis, Nolan identifies potential productivity and other losses for physician and facilities. RAND did not examine the possible loss of productivity for physician and other outpatient claims. We believe that there may be a productivity loss of outpatient and physician office-based services. The loss per claim may be very small, but because of the huge volume of physician and outpatient facility claims, the productivity loss may be significant.

To allow analysis of longer-term conversion impacts, HHS' estimates are moved to a year-by-year basis. Also, since we expect new procedures to be introduced each year, the savings from the introduction of the new codes are estimated to increase annually over the period for which the analysis was conducted.

For two benefit categories, ''fewer rejected'' and ''improper claims,'' RAND estimated a net cost of zero over the first 5 years, expecting that there would be some short-term losses before benefits materialized. For the purpose of calculating both year-by-year estimates and 10-year estimates, these categories are included on the cost side as well as on the benefit side. This is reflected by including costs of rejected and improper claims for the first 2 years.

The next section details the assumptions used to estimate the costs and benefits, and the models used to estimate the benefits. Upper and lower bound estimates are also presented.

4. Assumptions Underlying the Cost and Benefit Analysis

The estimates for the impact of replacing ICD–9–CM with ICD–10–CM and ICD–10–PCS code sets as the HIPAA standard code sets is based primarily on the RAND analysis previously cited. After reviewing that report versus other reports (for example, Nolan), comments from other entities, experience from other countries, and conversations with government analysts, we adapted the RAND results as the base for developing the regulatory impact estimates. As noted above, we adopted the RAND approach and results but made several modifications to the underlying RAND estimates.

5. Impacted Entities

Entities covered under HIPAA would be required to comply with the provisions of this proposed rule once finalized. Covered entities include all health plans, all health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard. In the sections that follow, we attempt to outline the ICD–10 transition cost impacts to various covered entities; however, we acknowledge that the cost analysis for training, productivity loss, and system changes are impacts of varying degrees on all covered entities.

There are multiple ways to implement the ICD–10 code sets. As the codes will be integrated into systems and

[9] ''ICD–10–CM Field Testing Project.'' AHIMA/AHA; September 2003 (*www.ahima.org/icd-10/documents/FinalStudy/pdf.*), accessed 8–12–08

[10] ''The Costs and Benefits of Moving to the ICD–10 Code Sets.'' Martin Libicki and Irene Brahmakulaum, The RAND Corporation. MHHSh 2004.

[11] ''Replacing ICD–9–CM with ICD–10–CM and ICD–10–PCS: Challenges, Estimated Costs and Potential Benefits.'' Robert E. Nolan Company. October 2003.

processes, some providers, plans, and vendors may decide to populate the new codes throughout their entire system at once, or translate the codes on a flow basis as they are used. Integration of the codes in many cases will be determined by the extent to which the available granularity is needed in transactions.

Many small and specialty practices may continue to submit paper claims as well, using preprinted forms that include all of the appropriate codes required for use in such offices. In most instances small practices and direct billing practitioners may assign the diagnosis themselves and may include the ICD–10 code on the paper billing form. As time goes on, we anticipate that the industry will migrate to the full use of the more robust codes to realize the full benefit potential of ICD–10.

We solicit industry and other stakeholder comments on ICD–10 integration and use of workarounds.

6. Estimated Costs

As identified in both the Nolan and RAND studies, HHS estimates the following three basic categories of costs:

- Training.
- Productivity Losses.
- Systems Changes.

In general, costs may be categorized into one-time costs and recurring costs. In our analysis, some costs are considered one-time costs associated with conversion and training, which will be expended within less than a year. Other costs, such as the cost for additional claims processing resulting from errors and delays in implementing system changes, are projected to extend out for several years and are considered recurring costs. (see Table 13a) Both RAND and Nolan identify short-term (6 months or less) and long-term productivity losses (extending beyond the initial 6-month period).

For purposes of this analysis, we consider a primary estimate to include all estimated costs, and estimated benefits incorporating both one-time and recurring costs, extended over a 15-year period based on the data provided from the RAND and Nolan studies. (Please refer to Table 13a and b for more information on costs and benefits as well as primary estimates).

In developing our estimates for both the costs and benefits of converting to the ICD–10 codes, we developed ranges, intended to express the uncertainty in our point estimates. The low point of each range represents for the most part, half of the point estimate, with the high point of the range representing a doubling of the point estimate.

For some of the cost estimates, we use the higher end of the scale to be more conservative. For example, when we suggested that training would take four to eight hours, we based our calculations on eight hours. Also, we use a 15-year timeframe to show the point at which benefits exceed costs. For purposes of this impact analysis, in some instances we base our ranges on that of the RAND study and extend them out over 15 years. Also, because our analysis shows that costs will be expended within the first 3–5 years, in most cases we use the midpoint of our ranges for the primary estimate.

We also estimate that there will be a phase-in of costs. In most cases, costs begin showing in the 2 years prior to implementation and zero out the year after implementation. The only exception is the costs for improper and returned claims, which we estimate will not be incurred until after implementation since claims using ICD–10 will not be submitted until after the implementation date.

In terms of a phase-in of benefits, we do this in order to show that benefits will increase the more the industry becomes familiar with using the new codes. We do not expect benefits to begin until the year after implementation, but will continue to increase each year thereafter with 100 percent of the benefit being realized 5–6 years after implementation.

Since we base our figures on 2004 dollars, for purposes of this analysis, we account for inflation by increasing the cost estimates by the Consumer Price Index (CPU–I) figures from 2004 to 2007 and the benefit estimates by the growth rate in the National Health Expenditure accounts for 2005 to 2007.

For estimation of the costs estimates, we divide the CPI–U annual index for 2007 by 2004's index to determine the adjustment factor in which to apply to each cost estimate and range. This adjustment factor equals approximately 1.098.[12] Since the cost estimates for implementing ICD–10 are not tied to medical services, we feel that the CPI–U is reasonable to use for adjusting for inflation. That is, most of the costs are so heavily allocated to the first few years, the inflation adjustment does not have a significant effect.

For the benefit growth factor pre-implementation, we use the growth in national health care expenditures for years 2005–2007, with year 2007 having an estimated growth rate of 1.212. For the growth projections for years 2012 and beyond, we use the compounded growth in the U.S. population which is projected to grow at 0.008 per year.[13]

Although we base most of our assumptions on the RAND study, we take into account the concerns expressed by the Nolan study that RAND did not raise:

- Cash flow.
- Contract renegotiations.

We agree with Nolan's assumption that the slowdown associated with the implementation of the new code sets may cause serious cash flow problems for providers. The risk of a payment slowdown always exists whenever a new payment system or policy is implemented. However, even with major policy changes, plans have learned over time to anticipate these problems and have instituted measures to provide periodic interim payments (PIP) for providers who may be affected by the processing slowdown. Most payers have learned through experience the cash flow needs of their providers and can easily set up PIPs and perform reconciliation at the end of the fiscal year.

With respect to contract renegotiation, this is an activity that providers and payers must perform on a regular basis, and every time a new policy is issued. The implementation of the new codes would require contract renegotiations. However, we do not see the level of effort to be significantly greater than with other renegotiation efforts, especially in the recent past with the initiation of a number of prospective payment systems for long-term care, psychiatric, rehabilitation, and outpatient services.

Therefore, for purposes of this impact analysis, we do not address the concerns of Nolan as stated above.

a. Training

For training costs associated with the ICD–10 transition, we account for both full-time and part-time coders. We surmise that full-time coders are primarily dedicated to hospital inpatient coding while the part-time coders work in outpatient ambulatory settings. The classifying of hospital inpatient coders as full-time may roughly represent the employment status of this group of coders. However, we believe it is more accurate to categorize coders based on their job location as inpatient or ambulatory setting coders. The difference in categorizing coders based on the job setting rather than full- or part-time has to do with the need to learn ICD–10–

[12] From the Consumer Price Index 2004 and 2007, *http://www.bls.gov/CPI/*, accessed 8–12–08.

[13] National Health Expenditures and Selected Economic Indicators, Levels and Annual Percent Change: Calendar Years 2002–2017.

PCS in addition to ICD–10–CM. All coders will need to learn ICD–10–CM while the coders working in the hospital inpatient setting will also need to learn ICD–10–PCS. This will apply to inpatient coders regardless of their status as part-time or full-time coders.

For full-time/inpatient coder training, we use the estimation calculated by AHIMA and others that getting full-time coders to proficiency on both ICD–10–CM and ICD–10–PCS could take as little as a few days or up to a full 40 hours.[14] Based on AHIMA membership, we assume that 50,000 full-time hospital coders would need one week of training, at $2,750 per coder, which includes $2,200 for lost work time and $550 for training expenses, for a total of $137.51 million.[15]

Therefore, we estimate that the training costs for full-time coders associated with adopting ICD–10 is approximately $137.51 million with a low range estimate of approximately $110 million and a high of approximately $165 million.

As explained previously, we expect training of full-time coders to start in 2010 (the year before ICD–10 implementation). We assume that 15 percent of training costs will be expended in this year. In the following year (the year ICD–10 implementation occurs), we assume 75 percent of training cost will be expended in 2011 and 10 percent of training costs in 2012.

Estimating the distribution of coders in ambulatory settings is more complicated because not every ambulatory setting may employ a coder. In many physician and practitioner offices, the use of ''super-bills''—preprinted forms that include all of the appropriate codes required for use in such offices—minimizes the need for a coder. Based on our knowledge of the industry, in most instances physicians and direct billing practitioners will assign the diagnosis themselves and may include the ICD code on the billing form. Yet we believe that all but the smallest practices will have someone whose responsibilities either formally as part of their job description or informally include handling coding issues.

Table 7 below summarizes the number of part-time coders by North American Industry Classification System (NAICS) code for ambulatory entities (*http://www.census.gov/csd/susb/susb05.htm,* accessed 8–12–08).

TABLE 7—AMBULATORY ENTITIES ASSUMED TO EMPLOY PART-TIME CODERS BASED ON THE 2005 STATISTICS OF U.S. BUSINESSES

NAIC code	Type of entity	Total number of entities (establishments) and employees[16]	5–9 employees	10–19 employees	20–99 employees	100–499 employees	Total number of part-time coders
6211	Office of Physicians	213,611	44,457	25,178	21,500	7,062	.....
	Employees	2,041,704	286,741	316,111	555,259	256,996	100,875
6213	Office of Other Health Practitioners.	115,378	19,357	7,654	5,043	11,774	.....
	Employees	553,658	121,527	88,196	96,754	47,155	30,962
6214	Outpatient Care Centers	26,901	1,897	1,907	4,190	5,440	.....
	Employees	658,507	12,510	24,766	109,237	186,883	17,941
6215	Medical and Diagnostic Laboratories.	11,856	1,324	1,324	1,492	928	.....
	Employees	222,651	8,577	13,194	41,707	40,221	6,080
6216	Home Health Care Services ...	20,184	1,426	1,569	4,109	2,445	.....
	Employees	913,514	9,558	22,111	171,704	245,827	.....
							179,267

Based on the 2005 Statistics of U.S. Businesses data, our analysis suggests that there are approximately 179,000 part-time coders who will require training on the ICD–10 CM codes, but not on the ICD–10–PCS codes. Based on contacts with industry and our own experience, we assumed that for every 20 employees employed in an ambulatory setting, there would be one part-time coder. Using the size categories that the Office of Advocacy in the U.S. Small Business Administration created with the Statistics of U.S. Businesses data, we calculated the number of part-time coders in outpatient ambulatory practices with 20 to 499 employees. (*http://www.census.gov/csd/susb/susb05.htm,* accessed 8–12–08) We further assumed, that based on their size, the administrative complexities and the types and volume of services provided, that facilities with 500 or more employees would require full-time coders. Thus, we did not include ambulatory practices with 500 or more employees in our analysis of part-time coders.

We also assumed that very small providers with between 5–10 employees would have someone responsible to manage coding issues, who would need some amount of training. We assume that the 179,000 coders would have training costs per coder of $550. This includes $440 for lost work time and $110 for training expenses, for an estimate total of $98.5 million.[17]

For purposes of this impact analysis, we estimate the cost associated with part-time coder training in adopting ICD–10 is approximately $98.50 million, with a low range of approximately $55 million and a high range of $165 million.

Code users can include people outside of health care facilities—researchers, epidemiologists, consultants, auditors, claims adjudicator, etc. Users could also include people within health care facilities in areas such as senior management, clinicians, quality improvement, utilization management, accounting, business office, clinical departments, data analysis, performance improvement, corporate compliance, data quality, etc. AHIMA defines a user of coded data as anyone who needs to have some level of understanding of the coding system, because they review coded data, rely on reports that contain

[14] RAND, page 8.

[15] RAND, page 8.

[16] *http://www.census.gov/csd/susb/susb05.htm,* accessed 8–12–08.

[17] RAND, page 8.

coded data, etc., but are not people who actually assign codes.

We estimate that there are approximately 250,000 code users.[18] We assume that of these 250,000 only 150,000 work directly with codes and would require eight hours of training at approximately $250 ($31.25 per hour × 8 hours). We estimate training costs for code users at $37.50 million with a low range estimate of $27 million and the high range is $55 million.[19]

For physicians, we assume that only 1 in 10 physicians, or 150,000 (there were a total of 1.5 million physicians in the U.S. as of 2005 [20]), would require training. Based on our experiences and the testimonies of various providers, we estimate physicians would only need 4 hours of training, which is half of what RAND assumes, at $137 per hour. [21] However, after conversations with industry experts and various physician types, we believe that since it is likely that physicians will obtain ICD–10 training through hospital-sponsored staff in-services, county medical society in-services, continuing physician education programs, etc., which they would attend nonetheless, physician ICD–10 training costs will be even less. Based on the assumptions above, we estimate the cost associated with physician training for adopting ICD–10 is $82.20 million with range estimates including a minimum of $0 and a maximum of $165 million.

We invite the public to comment on our assumptions and to provide any data that may improve the accuracy of our analysis.

b. Productivity Losses

Productivity loss refers to the cost resulting from a slow-down in coding bills and claims because of the need to learn the new coding systems. [22] One can think of productivity loss as the number of additional staff hours that would be required to code the same number of bills and claims per hour before the code conversion. With the adoption of a new code set, there would be an initial loss in productivity. All personnel, including coders and practitioners, would be affected to some degree. Coders would be directly affected because of the need to learn new codes and definitions. Time would be lost, and undoubtedly some claims would require resubmission to payers as both providers and payers adjust to the new codes.

i. Inpatient

We assume that there would be a significant amount of short-term losses during the first 6 months after implementation. Beyond that point, we believe that productivity would return to its previous level. Studies from Canada and Australia have shown that the productivity losses disappeared within 6 months after transition to their versions of ICD–10.

According to a field test conducted by the American Health Information Management Association (AHIMA) and the American Hospital Association (AHA) in 2003 (*http://www.ahima.org/icd10/documents/FinalStudy_000.pdf*), coders reported no difference in the time it took to code the claims in 58 percent of the cases. Ninety-one percent of the remaining records took more than five additional minutes over the ICD–9 coding in part due to:

- Unfamiliarity with the index structure of ICD–10;
- Use of different main terms and sub-terms in ICD–10 versus ICD–9;
- Spending more time reviewing the medical record; and
- Having greater familiarity with ICD–9 than with ICD–10, as many coders had common codes memorized.

AHIMA concluded that the availability of much-improved coding tools, more training, and increased familiarity with ICD–10–CM would significantly reduce the amount of time needed to code records in ICD–10–CM, possibly to the point where ICD–10–CM actually may require less coding time than ICD–9–CM.[23]

Although the field study suggests a larger initial loss of coder productivity, the lack of training, the unavailability of user-friendly coding tools, and other limiting factors, it did not represent the ''real-world'' conditions under which coding would be performed. Because of the restrictions and the absence of the ''real world'' conditions under which we believe coders will be working once the ICD–10 code system is implemented, we did not base the estimate of productivity loss on the field study.

For purposes of this impact analysis, we estimate that it would take coders 1.7 additional minutes in the first month to code an inpatient claim that includes an inpatient procedure.[24] We estimate that the first month's productivity loss at 1.7 minutes per claim and applying this to 1.8 million inpatient claims requiring procedures per month (20,000,000 claims per year divided by 12 months) at $50 per hour or $1.41 per claim will result in productivity losses equaling $2.7 million in the first month. For purposes of this analysis, we assume that resumption of productivity will increase the same amount each month over the next five months. Dividing $2.7 million by 6 gives a monthly increase in productivity of $450,000. Thus, within 5 months following implementation of the ICD–10 codes for inpatient services, coding productivity will return to their pre-conversion levels and there will be no long-term impact on coding efficiency. After subtracting the $450,000 from each month's lost productivity, we add the residual monthly amount of lost productivity. The total cost due to reduced inpatient productivity resulting from introduction of the ICD–10–CM and PCS codes is projected to be $8.90 million incurred within the first year, with a low estimate of approximately $0 and a high estimate of approximately $55 million.

Further support for the view that long-term productivity will not be adversely affected came in a July 2007 conversation CMS had with AHIMA.[25] AHIMA further reiterated that long-term productivity losses would not be significant. The learning curve for ICD–10 in an inpatient setting may be longer due to the need for coders to learn both ICD–10–CM and ICD–10–PCS. However, ICD–10–PCS has proven to be easier for coders to learn than ICD–9–CM procedures with its many inconsistencies. Within 2 months, inpatient coders would understand ICD–10–CM and rapidly gain a proficiency in its use. Within 6 months, inpatient coders would be highly proficient in its use. After 6 months, there would be extremely small degrees of loss of productivity, if any at all.

ii. Outpatient

In analyzing the cost of productivity loss in the outpatient/ambulatory setting we had to determine the amount of additional time coders would need to code a claim with the ICD–10–CM codes, and the number of claims processed within a given period.

In selecting a source for the number of outpatient/ambulatory claims, we examined data from the National Ambulatory Medical Care Survey, the National Hospital Ambulatory Medical

[18] RAND, page 9.

[19] RAND, page 9.

[20] World Health Organization, *http://www.who.int/en/,* accessed 8–12–08.

[21] RAND, page 9.

[22] RAND, page 10.

[23] ICD–10 Field Testing Project Summary Report, September 23, 2003; AHIMA, p. 25.

[24] RAND, page 10.

[25] This was an informal conversation between Pat Brooks from the Hospital and Ambulatory Policy Group within the Centers for Medicare Management at CMS and Sue Bowman from AHIMA.

Care Survey and the Nolan report. These surveys collect data on patient visits to physicians and visits to hospital outpatient departments and emergency rooms. In 2005, the NAMCS reported 964 million physician visits. In the same year, the NHAMCS reported 115 million patient visits to emergency rooms and 90.4 million visits to hospital outpatient departments. The total number of patient visits to outpatient medical settings based on the two surveys was 1,169 million visits.

Because we are inclined to adopt a conservative approach to estimating the costs of converting to the ICD–10 codes, we are using the estimate of outpatient claims that the Nolan report used in its calculation. While the NAMCS and NHACS surveys probably accurately reflect the number of patient visits, the number of visits may understate the number of claims submitted. As we discuss below in section iv., Improper and Returned Claims, a certain percentage of claims will be processed more than once. We believe that the two billion claim estimate accounts for the multiple processing of claims in addition to the initial processing of claims.

For purposes of the analysis, we assume the average time to code an outpatient claim could take one-hundredth of the time for a hospital inpatient claim. The average time to code an outpatient claim takes into account the wide variety of outpatient settings and coding forms. For example, physician offices may use preprinted forms or touch-screens that require virtually no time to code. Clinics and hospital outpatient units using outpatient claim forms, however, may require more time and some may require as much time as inpatient claims.

Applying the estimate of 0.017 minutes per outpatient claim (one hundredth of 1.7 minutes for inpatient claims) to the monthly number of claims of 166.7 million and $50 per hour or $0.014 per claim, we estimate the first month's productivity loss will be $2.6 million. Applying a straight line assumption for the recovery or productivity over the next five months, we divided $2.6 million by six to arrive at $433,000. That is, productivity will recover from a low of $2.6 million at a rate of $433,000 per month for the next five months. Over the following 5 months, we expect productivity to return to its pre-conversion level.

In the same July 2007 CMS conversation referred to in the discussion of inpatient productivity loss, AHIMA noted that the productivity losses in an outpatient setting would be less than inpatient due to the need of coders to learn only ICD–10–CM rather than both ICD–10–CM and ICD–10–PCS. Within a few weeks, coders would understand most of the differences between ICD–9–CM and ICD–10–CM. Within 6 months, coders would be quite proficient in ICD–10–CM.

For purposes of this impact analysis, we estimate the cost associated with outpatient productivity losses with adopting ICD–10, is approximately $8.56 million with a range of a $0 minimum and a $55 million maximum.

iii. Physician Practices

We assume that physician practices will sustain an initial loss of productivity loss. Each practice will have to convert their current ''super-bills'' to an updated version that includes ICD–10 codes. AHIMA estimates that it will take approximately two hours for this conversion, with a one-time cost estimate of $55 per practice. Assuming there are 200,000 practices nationwide, this cost equates to a one-time total cost of approximately $10.98 million, with a low range of $5.5 million and a high range of $27 million. We consider this number to be high considering that some practices will have their specialty societies perform the ''super-bill'' conversion and supply it to their members.

iv. Improper [26] and Returned Claims

The implementation of the new code sets is expected to produce a temporary increase of coding errors especially on the part of physicians. To determine the effects of introducing code changes on the number of claims processing and the number of Medicare returned claims, we reviewed returned claims data for FYs 2004, 2005 and 2006. We found that there appears to be a pattern of a spike in Medicare returned claims 3 to 6 months following the introduction of ICD–9 annual code updates. The average percent increase in returned claims associated with the annual coding update is approximately three percent over the 3-year period.[27] Based on our findings and considering that the annual coding update affects a relatively small number of codes compared to the proposed ICD–10 conversion, which will affect all diagnostic and procedure codes, we anticipate that the percent of returned claims following the implementation could be more than double the previous years' increases. We expect that the percent of returned claims may peak at around 6–10 percent of the pre-implementation levels

Relying on RAND's estimate that the average overall cost of claims adjudication in the U.S. is roughly $22 billion nationwide per year,[28] this represents only a fraction of the $88 billion total health administrative claims adjudication costs.[29] If we assume that the average claim goes through two cycles, the overall cost of claims adjudication divided by the average number of cycles a claim makes, results in a cost of approximately $11 billion per cycle per year for all claims.[30] Based on our assumed cost of claims processing and the additional initial increase of 3 percent jump in erroneous claims, we estimate that the total cost for claims handling for plans and providers will be $543.29 million. We assume the annual cost of the increase in returned claims equals $329 million (3 percent of $11 billion). In the first year, we expect the full annual cost for added claims processing. In the second year, we expect added processing costs to equal 50 percent or $164 million. In the third year, we expect processing costs to equal 15 percent of the annual cost, or approximately $49.4 million. By the fourth year, however, we expect claims processing costs to begin to drop below their pre-conversion levels (see ''Fewer Rejected Claims'' and ''Fewer Improper Claims'' in the discussion of Benefits).

In the first year following implementation, claims processing costs for the added returned claims are estimated to be $329.29 million. The next year, we assume the number of returned claims will be half of the first year's level and will cost $164.64 million to process. By the third year following implementation, we assume that returned claims will be 15 percent of the first year's number and cost about $49.39 million.

With the transition to ICD–10, we assume that eventually there will be fewer returned claims due to the more detail and better structure that ICD–10 provides. Costs of returned claims may include improper claims that reflect an attempt on the part of suppliers and providers to ''game'' the system. That is, during the period following the transition, some suppliers and providers may attempt to abuse and possibly defraud the payment system, hoping that improperly coded claims may slip through plans' payment edits. In

[26] RAND defines improper claims as those claims that could be fraudulent.

[27] CMS Medicare Returned Claims Report for FYs 2004, 2005, and 2006; Office of Financial Management.

[28] RAND, page 25.

[29] The National Health Expenditure accounts for private health insurance cost of administering insurance are in claims adjudications.

[30] RAND defines a claim cycle as the process a claim goes through from provider to payer.

discussion of the benefits of implementing ICD–10, we have treated the benefits for fewer returned claims and fewer improper claims separately. In this section, we combine the cost of the initial increase in returned clams with the expected increase in improper claims. Therefore, for purposes of this impact analysis, we estimate that the lost productivity costs for improper and returned claims for transitioning to ICD–10, is $543.29 million with a range estimate of a $274 million minimum and a $1.1 billion maximum.

We invite the public to comment on our assumptions and to provide any data that may improve the accuracy of our analysis.

C. Systems Changes

Although system change requirements may vary, all would need to support the expanded number of characters in ICD–10–CM and ICD–10–PCS, as well as the number of available codes. Trading partner agreements and reimbursement policies would also impact system changes.

In implementing the ICD–10–CM and PCS coding systems, large providers and institutions will probably need to make changes to their systems as well as perform software upgrades, while small providers may require only software upgrades.

i. Providers and Software Vendors

Large provider groups, chain providers, and institutions, such as large hospitals, are most likely to require changes to their billing systems, patient record systems, reporting systems and associated system interfaces. For example, mainframe-based systems will require changes to accommodate the longer diagnostic and inpatient procedure codes which, in turn, will require changes to interfaces with other systems such as accounting and medical records. The new codes may also require the redesign of standard and special reports. Small providers who rely on super-bills, as well as their home-grown systems for capturing patient information and claims submission, may only need to update their systems to accommodate the length of the new codes. Given the information above, we expect that system changes will incur costs in the range of $55 million to $220 million.[31] Factors that contribute to the range of costs include: The degree of system integration; the need for outside technical assistance; and the number of systems and system interfaces that must be updated.

We assumed that implementation of the system changes upgrades would begin as early as 2 years in advance of the ICD–10 implementation date. We expect that large providers especially would need to begin this far in advance and that spending on system change in 2009 would equal $20.58 million and would represent 15 percent of total provider system change costs. In the next year, spending would double to 30 percent of provider system change expenditures and equal $41.16 million. In FY 2012, the year ICD–10 is to be implemented, we anticipate spending for system changes to amount to 50 percent of provider spending on system changes and equal $68.60 million. The year following implementation, we expect providers and suppliers with small systems and some large organizations will still be implementing changes or refining their changes. In that year, we are assuming that about 5 percent of the provider system change costs will be expended or $6.86 million. Thus, for purposes of this impact analysis, we estimate that from 2009 through 2012, the cost of system changes to providers for transitioning to ICD–10, is approximately $137.20 million, with a low range estimate of $55 million minimum and a $220 million maximum.

For small providers that are PC-based or have client-server systems that rely on vendor-supplied software, the provider may not bear any immediate costs for the software upgrades. Based on CMS's own experience with the industry, most software maintenance contracts offer free upgrades to accommodate regulatory changes. Thus, the impact on providers that have such contracts will be postponed until the contract is renewed. Even if a provider were to pay for the software upgrade directly, an ambulatory provider would only require updating of the diagnostic codes.

While many providers who use vendor-supplied software may be able to defer the costs of software upgrades, the vendor industry may have to bear, at least initially, the costs of such upgrades. In interviews RAND conducted with industry experts including association representatives, providers, payers, software and service vendors, and government officials, two major software vendors said it would take 10 percent of their labor force, one saying it would be spread out over a 3-year period. Another stated that it would take 50 to 100 person-years.[32] Several other software vendors that RAND interviewed, however, stated that they expect that adaptation to the ICD–10 codes would only take a few person-years. Thus, based on RAND, we estimate the cost of system changes for software vendors of transitioning to ICD–10, to be approximately $96.05 million with a range of $55 million minimum and $137 million[33] maximum because of the wide range of information and billing systems and the configurations of provider systems.

As in the case with provider and supplier system change costs, we assume that beginning in FY 2009, software vendors will begin developing new software and continue the development and refinement through FY 2013. In FY 2009, vendors are assumed to spend 15 percent of the cost of software development or $14.41 million. In FY 2010, we anticipate vendors will spend 30 percent of the cost of software development or $28.81 million and in FY 2012, the year of implementation, we project vendors will expend 50 percent or $48.02 million. In the next year, spending will continue mostly for refinement and last minute upgrades. The expenditures are calculated to be $4.81 million and represent 5 percent of the software development costs.

ii. Payers

We estimate that changing payer systems to ICD–10 may be one of the largest cost categories, but the cost is not clear and the range is variable as payers represent a widely varied group. System change costs for payers are based on interviews that RAND conducted with eight different payers. (However, the ''List of Interviewees'' in Appendix B of the RAND report lists seven different payers, with a total of nine interviews). RAND divides the eight payers into three groups, based on their approach and estimate for system change. RAND does not disclose which payers fall into which of the three groups. The first group, which consists of three payers, representing 4 percent of the market, expects their vendors to supply the updates. The second group, which consists of three payers, representing 12 percent of the market, notes they would invest 40 cents per member. The third group, which consists of two payers, representing 3 percent of the market, estimates costs to be $1 per member. Using RAND's basic findings, we estimate the cost of system changes to payers for transitioning to ICD–10, is approximately $164.64 million with a range of $110 million minimum to $274

[31] RAND, page xiv.

[32] RAND, page 5.

[33] RAND, page xiv and page 17.

million maximum, based on the groups' market share estimates from RAND.[34]

iii. Government Systems Costs

Government systems change estimates are expected to occur across a number of Federal and State agencies and include Federal transition costs. Also, to make costs comparable to those of the private sector system changes, only costs for logic and format changes are considered. The examples in this impact analysis are only illustrative in nature and are based on limited analysis. They are presented to illustrate the potential administrative costs to the Federal Government.

For purposes of this impact analysis, we gathered information from various government agencies to determine total government systems costs for implementing ICD–10. Estimates for State Medicaid Agencies were gathered from the Center for Medicaid and State Operations (CMSO) within CMS and were derived based on the state's need to design, develop and implement changes to their systems to accommodate ICD–10 codes. Some government agencies are continuing to work on their cost estimates. As this information is still in the process of being analyzed and compiled, it is not included for purposes of this impact analysis. The costs outlined in Table 8, represent our best estimate based on the information available from CMS, the Indian Health Service (IHS), State Medicaid Agencies, and the Department of Veteran's Affairs (VA).

For purposes of this impact analysis, we estimate costs for the impact on government systems in transitioning to ICD–10 include system modifications, payment modifications, updates to software applications and training for a total minimum cost of approximately $315 million, with a minimum estimate of $157.5 million and a maximum estimate of $630 million. Table 8 shows the cost breakouts by government agency.

TABLE 8—GOVERNMENT COSTS

Change	Government agency	Cost (in millions)
Systems/Software Modifications and Updates:		
	CMS	$105
	IHS	8
	VA	19.05
Subtotal		132.05
Training:		
	CMS	9.5
	IHS	1.3
	VA	47
Subtotal		57.8
Planning:		
	CMS	4
	IHS	3
	VA	2.5
Subtotal		9.5
Other		12.6
State Medicaid Agencies		102
Total		315

We invite public comment on our assumptions, as well as comments from affected government agencies herein identified or those not identified in this analysis, so they may provide any additional and/or updated data that may improve the accuracy of our analysis.

(d) Distribution of ICD–10 Transition Costs

In the Table 9, we show the distribution of the transition costs to the ICD–10 codes for providers, suppliers, payers and software and system design firms. Entities are grouped by the North American Industry Classification System (NAICS) and are presented at the firm level. The NAICS figures were adjusted based on the same medical inflation factor we used for all costs that are outlined above.

As indicated earlier in this analysis, data was collected primarily by inpatient and outpatient categories (see Table 9). To allocate the transition costs, we have to use an available base which can serve as a proxy for apportioning the transition costs to the sub-groupings of inpatient and outpatient providers and suppliers. For the task of allocating the transition costs, we are using the revenue-receipts reported in the Services Annual Survey and the National Health Expenditure Accounts.

The first step was to group providers and suppliers by inpatient and outpatient groups reflecting the level at which the data was available. Inpatient providers included:

- Hospitals,
- Nursing facilities.

The group of outpatient providers and suppliers included:

- Physicians and other practitioners (excluding dentists),
- Outpatient care centers,
- Medical and diagnostic imaging services,
- Home health services,
- Other ambulatory health care services,
- Durable medical equipment suppliers.

In column 3, we present the revenue-receipts for each type of provider-supplier, insurance carrier-third party administrator, and computer design firm expected to bear transition costs. We summed the revenue-receipts for each of the inpatient and outpatient.

Column 4 shows the percent of the two groups' revenue-receipts each

[34] RAND, page 14.

provider-supplier type comprises of the group's total.

In column 5, we apply the percentages to the total ICD–10 transition costs for each provider-supplier type. Total inpatient transition costs—including productivity losses—from Table 9 equal $228.55 million. Total transition costs—including productivity losses—for outpatient providers-suppliers (from Table 9) equal $165.36 million, including an adjustment for inflation. It should be noted that physician costs include a portion of the coding training costs and productivity losses in addition to costs directly allocated to physicians and practices expenses. This explains the high percent of implementation costs to receipts-revenues than for the other outpatient providers-suppliers.

TABLE 9—ESTIMATED IMPACT OF ICD–10 TRANSITION COST ON INPATIENT AND OUTPATIENT PROVIDERS AND SUPPLIERS (ADJUSTED FOR INFLATION)

NAICS	Provider/supplier type	Firms	Revenue/ receipts ($ mil.)	Percent of revenue receipts	ICD–10 costs ($ mil.)	Percent ICD–10 costs of revenue/ receipts
622	Hospitals (General Medical and Surgical, Psychiatric and drug and Alcohol Treatment, Other Specialty).	4,409	653,033	81.45	186.16	0.03
623	Nursing Facilities (Nursing care facilities, Residential mental retardation, mental health and substance abuse facilities, Residential mental retardation facilities, Residential mental health and substance abuse facilities, Community care facilities for the elderly, Continuing care retirement communities).	22,867	148,716	18.55	42.40	0.03
	Subtotal	27,276	801,749	100	228.55	0.03
6211	Office of Physicians (firms)	189,542	330,889	61.60	137.62	0.04
6214	Outpatient Care Centers (Family Planning Centers, Outpatient Mental Health and Drug Abuse Centers, Other Outpatient Health Centers, HMO Medical Centers, Kidney Dialysis Centers, Freestanding Ambulatory Surgical and Emergency Centers, All Other Outpatient Care Centers).	13,624	73,966	13.80	9.93	0.01
6215	Medical Diagnostic and Imaging Services.	7,811	37,253	6.93	5.00	0.01
6216	Home Health Services	14,512	47,007	8.75	6.31	0.01
6219	Other Ambulatory Care Services (Ambulance and Other).	5,872	24,593	4.58	3.30	0.01
N/A	Durable Medical Equipment [3]	404,293	23,709	4.41	3.18	0.01
	Subtotal	636,654	537,417	100	165.36	0.03
524114, 524292	Health Insurance Carriers and Third Party Administrators [4].	4,578	723,412	100	164.54	0.023
5415	Computer System Design and Related Services [6].	97,556	200,695	100	96.50	0.048
	Subtotal	102,134	924,107		261.00	0.044
	Total	575,522	2,263,273		655	0.031

Table notes: Most of the data for this table comes from the Statistics of U.S. Businesses 2005 tables for firms and establishments presented by employee size, and from the Bureau of the Census Services Annual Survey for 2006 that provides annual receipt-revenues by NAICS. Both data sets are available from *http://www.census.gov/econ/www.index.html*. Data on the number of Durable Medical Equipment suppliers comes from the 2007b CMS Data Compendium *http://cms/hhs.gov/DataCompendium/17_2007_Data_Compendium.asp#TopOfPage.* Revenue data comes from the National Health Expenditures tables, 1960–2006, available at *http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage*. All accessed on 8–12–08. Firms data come from *http://www.census.gov/svsd/www/services/sas/sas_data/sas54.htm*, accessed 8–12–08.

Revenue and receipts for each industry sector and sub-sector come from the Census Bureau Services Annual Survey for 2006 at B29. Revenue/receipt data for NAICS codes 6211–6219, 622 and 623 come from tables 8.1–8.10. Data for codes 5415 come from tables 6.1–6.21. Revenue/receipts are used to allocate ICD–10 implementation costs. Revenue/receipts were subtotaled by ambulatory provider plus DME suppliers (NAICS 62111–6219) and inpatient providers (NAICS 622, 623) and the percent of the subtotaled revenue/receipts for the provider/supplier was computed and applied to the total ICD–10 implementation costs for each of two subtotaled groupings. ICD–10 costs for ambulatory provider do not include the cost of system changes. Some costs, however, are included with inpatient system changes since large multi-campus, integrated health care facilities are likely to include their ambulatory care facilities in the cost of upgrading their information systems.

In calculating the impact on provider/suppliers, payers, third party administrators and computer design and related service firms we compared the total expected costs to the one-year revenues for each class of entities. By

doing so, we deliberately overstate the expected annual impact of the transition. In part, we did this because we cannot be certain that we have properly allocated implementation costs to each entity category or that we accounted for all costs.

The impact on revenue-receipts of the transition to ICD–10 is shown. For inpatient providers, the impact will be an average increase against revenues of 0.03 percent. For outpatient providers and suppliers, the average increase against revenues is projected to be 0.03 percent.

The impact on insurance carriers and third party administrators is expected to be an increase against revenues of 0.023 percent. For system design firms, the impact against revenues is projected to be 0.048 percent.

Because we are not able to determine the exact number of third party administrator firms or system design firms that will be involved or have to implement the ICD–10 codes, we used the number of firms and revenues-receipts shown for the applicable NAICS. To the degree that fewer firms are actually involved in the transition to ICD–10, our estimate of the impact is understated. The fewer firms implementing ICD–10, the smaller number firms over which to spread the implementation costs. Therefore, we are specifically requesting comments on this estimate and how many third party administrators and computer design firms will be implementing ICD–10.

Table 10 outlines the approximate total estimated costs as outlined in the above sections. Table 10 shows both the minimum and maximum ranges for each cost as well as their corresponding primary estimates. We solicit comments from industry and other stakeholders on other potential entities that may be affected by the transition from ICD–9 to ICD–10 code sets.

TABLE 10—SUMMARY OF TOTAL ESTIMATED COSTS

[In millions]

	Minimum	Maximum	Primary estimate
Training:			
Full-time Coders (Inpatient)	$110	$165	$137.51
Part-time Coders (Outpatient)	$55	$165	$98.50
Code Users	$27	$55	$37.50
Physicians	$0	$165	$82.20
Productivity Losses:			
Coders (Inpatient)	$0	$55	$8.90
Coders (Outpatient)	$0	$55	$8.56
Physician Practices	$5.5	$27	$10.98
Improper and Returned Claims	$274	$1,100	$543.29
Systems Changes:			
Providers	$55	$220	$137.20
Software Vendors	$55	$137	$96.05
Payers	$110	$274	$164.64
Government Systems	$157.5	$630	$315.00

7. Projected Benefits

We identified six benefits of transitioning to ICD–10: [35]

- More accurate payments for new procedures:
- Fewer rejected claims;
- Fewer improper claims;
- Better understanding of new procedures;
- Improved disease management;
- Better understanding of health conditions and health care outcomes (no monetary estimate made); and
- Harmonization of disease monitoring and reporting world-wide (no monetary value was included in the analysis).

In our analysis, benefits begin to appear in the year following the implementation date. Therefore, our total estimated benefits differ slightly from RAND estimates, which assumed phased-in benefits prior to implementation. All benefit estimates, in addition to having a point estimate also have a wide high to low range because of the uncertainties inherent in these estimates. We have also adjusted benefit figures for the projected growth in the population using the growth in national health care expenditures for years 2005–2007. Year 2007 is an estimated growth rate of which we used an adjusted growth factor of 21.2 percent. For the growth projections for 2012 and beyond, we used the compounded growth in the U.S population which is projected to grow at 0.8 percent per year.

a. More Accurate Payments for New Procedures [36]

The transition to ICD–10–PCS codes will allow for more accurate payments for new procedures. Under the current ICD–9 Volume 3 procedure codes there is little room for additional codes. It has been estimated that at the current rate of adding additional codes, the capacity of ICD–9 Volume 3 will reach its maximum by 2009. The result is that new and possibly more complex and expensive procedures are being grouped in with less expensive procedures. With introduction of the PCS codes, it is more likely that such new procedures will receive a separate code and more appropriate payment. We assume that new procedures that could receive a separate code under the PCS system are so expensive they would be unlikely to be performed unless, through the new coding, the hospital received adequate payment.[37]

Of the approximately 20 million procedures performed each year, roughly one percent or 200,000 procedures are new. We estimate that 100,000 of the new procedures would be paid for by CMS based on the fact that Medicare pays for approximately one half of all inpatient procedures. Examining the historical trend for the number of new codes assigned each year, we determine that about one percent of new procedures received separate codes. Using this one percent assumption, the 200,000 new procedures would be represented by approximately 36 new codes (one percent of the 3,600 current procedure

[35] RAND, page 19.

[36] RAND, page 21.

[37] RAND, page 21.

codes in the ICD–9 Volume 3). We assume that three procedures would be performed frequently enough to be given their own codes. We also assume the three procedure codes would represent about 40 percent of the annual number of new procedures.[38]

Subtracting out 40 percent of the procedures from 100,000 new procedures that CMS would pay for each year leaves 60,000 procedures represented by 33 codes that, under the current coding structure, may be inappropriately grouped and paid an inappropriate amount. For purposes of this analysis, we recognize that the odds that hospitals would not perform a procedure that was seen to have therapeutic value in spite of being underpaid are low. For this reason, we assume that in 10 percent or 6,000 of the cases involving new inpatient procedures that are not adequately reimbursed, hospitals may be disinclined to admit patients requiring the procedure.

Finally, we estimate the opportunity cost of foregoing those procedures that would be undervalued under the current coding structure (and presumably would be properly paid under the PCS codes). Of 33 procedures that are undervalued, some may yield significant health benefits while the majority will yield small health benefits. Hospitals are more likely to perform the high benefit procedures even though they may be underpaid for the procedures.

We assume that the average procedure costs approximately $12,120 and has a net benefit yield of $6,060. Multiplying the amount by the 6,000 procedures yields a benefit of approximately $36 million.[39] We also expect that the effects of the benefit are cumulative for each year and that every year, 6,000 procedures will be added.

Based on a growth rate of 6,000 per year, the growth in benefits would equal 50 fold or $1.8 billion in 10 years. This may overstate the benefits because of cost reduction over time due to the learning curve and the introduction of lower cost alternative procedures. Rather than an increase of 50 times, a factor of 25 is used, resulting in an estimate of $909 million. For purposes of this impact analysis, we make a more conservative assumption. After the third year following implementation of the code conversion we assume an opportunity cost that increases $12 million every year, with the fourth year showing approximately $62 million benefit (see Table 13b). For purposes of this impact analysis, we estimate that the benefit of more accurate payments for new procedures would equal approximately $1,032 million with a minimum range estimate of $121 million and a maximum estimate of $1,455 million.

We recognize that many assumptions underlie our estimates of more accurate payments and we invite comments on this analysis.

b. Fewer Rejected Claims

The Workgroup for Electronic Data Interchange (WEDI) has stated that ''[The] greater detail [of ICD–10–CM and ICD–10–PCS] may help reduce the number of cases where copies of the medical record need to be submitted for clarification for claims adjudication.'' [40] For example, in ICD–10–CM, the injury codes provide excellent detail in identifying the fracture site of a malunion or non-union; the ICD–9–CM codes for malunion and non-union do not identify fracture site. If the payer required this information to adjudicate the claim, the provider would need to send a claims attachment. Also, in ICD–10–CM, the injury codes provide excellent detail in identifying bilateral fractures. If a patient fractured both wrists, two codes could be assigned; one code identifying the left wrist fracture and a separate code identifying the right wrist fracture could be reported. ICD–9–CM does not provide this detail and if a provider wanted to report fractures of both wrists and reported the diagnosis code twice, the claim would be rejected.

Based on the WEDI assumption, we estimate the average cost per cycle of processing a claim at a total of $12 billion per year for all claims. RAND makes the assumption that using ICD–10 code sets would decrease the amount of claims sent back by one percent. This gives a $120 million annual benefit (0.01 x 12 billion).[41]

For purposes of this impact analysis, we estimate approximately $100 million per year in benefits after phased-in benefits for the first four years, compounded annually by a 0.8 percent growth in the population. We assume an extended phase-in for this benefit because of the lag time in receiving claims data showing the effects of the new system that will lead to delays in taking advantage of the improved and more precise data.

We also assume that returned claims will temporarily increase in the initial years. We discussed the temporary increase of returned claims in section b. iv., above, under Productivity Losses.

For purposes of this impact analysis, we estimate that the benefit of fewer rejected claims would equal approximately $1,015.41 million with a minimum range estimate of $242 million and a maximum estimate of $3,031 million. We invite the public to comment on our assumptions and to provide any data that will improve the accuracy of our analysis.

c. Fewer Improper Claims

The distinction that we are seeking to make in this section is between claims that would be returned because of mistakes in coding resulting from confusion about the new codes, lack of training and experience with the new codes, and those claims that appear to be deliberately miscoded in an attempt to defraud or abuse the payment system. WEDI states that, despite an initial expectation of increased improper claims, ''In the longer term, it is possible that fraud could be reduced since ICD–10–CM and ICD–10–PCS are more specific and there are fewer 'gray' areas in the coding.'' [42] The amount of improper claims due to abuse is estimated to be $3.03 billion annually, approximately 20 percent of the $15.8 billion that GAO estimates are improperly paid each year.[43] GAO acknowledges that this number may not represent all improper payments. Given this, we assume that eight percent of payment system abuse is perpetrated by people who capitalize on the ambiguity of the ICD–9–CM codes.[44] We also assume that half of that eight percent would feel that the new codes would eliminate the ambiguity, eliminating half of these abuses, assuming that new ambiguities are not created.

We estimate that after phased-in benefits in the first four years after implementation, which compounded annually by an 0.8 percent population growth factor, 100 percent of the benefit will be reached in the fifth year after implementation. We assume an extended phase-in for this benefit because of the lag time in receiving claims data showing the effects of the new system that would lead to delays in taking advantage of the improved and more precise data.

For purposes of this impact analysis, we estimate that the benefit of fewer

[38] RAND, page 22.

[39] RAND, page 23.

[40] ''Issues Surrounding the Proposed Implementation of ICD–10.'' WEDI MHHSh 2000, page 9.

[41] RAND, page 23.

[42] RAND page 26.

[43] RAND, page 26 and GAO, Federal Budget, ''Opportunities for Oversight and Improved Use of Taxpayer Funds,'' Statement of David M. Walker, Comptroller General of the United States, GAO–03–922T, *http://www.gao.gov/new.items/d03922t.pdf*, accessed 8–12–08.

[44] RAND, page 26.

improper claims will equal approximately $508.22 million, with a range minimum estimate of $121 million and a maximum estimate of $1,455 million.

As with rejected claims, this benefit is also expected to be an initial cost as people take advantage of the ambiguity during transition to ICD–10 code sets. For purposes of this impact analysis, there may be a greater number of returned claims as well as an increase in the percentage of initial improper payments. In Table 13a, we show the expected effects of the initial impact of rejected and improper claims. We invite the public to comment on our assumptions and to provide any data that may improve the accuracy of our analysis.

d. Better Understanding of New Procedures [45]

Benefits are also anticipated due to better understanding of new procedures with ICD–10. The rationale is that ICD–10's granularity would aid statistical analysis and provide more information on disease treatments and outcomes. We estimate the number of procedures that would be identified only in ICD–10–PCS and would provide statistically significant differences in outcomes. That is, identification of procedures through the use of the ICD–10 codes could presumably enable statistical analysis of procedures that would not otherwise be possible and thereby become the subject of research. Through a series of assumptions regarding 200,000 occurrences of the ''significant'' new procedures that would be added each year (see the discussion above regarding more accurate payment for new procedures), we pare the number of procedures that would actually be changed as a result of research down to 16,000 procedures.[46] The assumptions apply to the elimination of high volume procedures (again, see the discussion on more accurate payment for new procedures), the probability that anomalies would be discovered only through the application of ICD–10 codes and that finally such anomalies would result in the change in medical practice. The results of the research could indicate that procedures that were considered appropriate are now found to be inappropriate for the patients that underwent the procedure. Similarly, the research may find that procedures that were believed to be inappropriate may now be thought to be appropriate.

Finally, applying the same net benefits used in the analysis of more accurate payments of new procedures, we conclude after phased-in benefits in the first three years following implementation, which compounded annually by an 0.8 percent growth in the population, 100 percent of the benefit will be realized in the fourth year.

For purposes of this impact analysis, we estimate that the benefit of a better understanding of new procedures with implementing ICD–10, would equal approximately $812.54 million with a minimum range estimate of $121 million and a maximum estimate of $1,819 million. We invite the public to comment on our assumptions and to provide any data that may improve the accuracy of our analysis.

e. Improved Disease Management [47]

Disease management programs are generally used for managing chronic diseases to prevent or delay serious complications. The increased granularity of ICD–10–CM would allow case management organizations to better identify candidates for disease management programs, and to better adapt the disease management program to the individual once enrolled. To estimate improvements in disease management that the ICD–10 conversion could bring about, we follow RAND's use of diabetes as the sample disease and their assumption that two-thirds of all the benefit would come from better management of this disease.

For purposes of this analysis we follow the RAND model that divides diabetics into Type I and Type II not currently in a disease management plan and who could benefit from participating in such a plan; and those in a disease management plan and who could benefit from improved management of their disease. RAND makes the following assumptions:

- 60 percent of diabetics are currently enrolled in plans with disease management programs;
- 50 percent of the patients in such plans are not in a disease management program (30 percent);
- 50 percent of plans use a system other than ICD to identify and classify their patients. Of the remaining half, 2/3 use (1/3 of the total) use ICD classifications;
- Use of ICD–10 reveals new information on 20 percent of Type II diabetics in plans using ICD classifications;
- 50 percent of these patients elect to participate in the disease management program;
- 20 percent of those newly enrolled in a disease management program, achieve sufficient improvement to increase their life expectancy by six months.
- For patients already in a disease management program, using ICD–10 will result in an improved program in 50 percent of the patients.
- 10 percent of Type I and Type II will achieve improvements to the point of Type I achieving two additional years of full quality life and Type II six additional months of full quality life.

We estimate the number of both Type I and Type II diabetics at 1.2 million and 22.8 million,[48] respectively. Using these numbers as a base, we can arrive at an annual estimate of benefits. Applying RAND's formulas in this case, we determine that approximately 45,144 Type II individuals per year who would gain six months of full quality of life valued at $100,000 per year.[49] This yields a benefit of $2.257 billion ($50,000 × 45,144) for those Type II diabetics not currently enrolled in a disease management plan but who would be enrolled as a result of the conversion to the ICD–10 codes.[50]

The benefit of the greater granularity that use of ICD–10 codes may offer for those who are currently enrolled in a disease management plan is greatly dependent upon how much the additional detail helps the enrollee, and how many enrollees are helped. We could create an assumption for the percentage of people who would be enrolled in a better plan based on the new information that ICD–10 codes may provide, and the percentage of those whose treatment would be adjusted in response to the new information.[51]

We could potentially conclude that adding someone to a diabetes management program has twice the benefit of adjusting treatment for someone already enrolled in a disease management program. As a result of the code conversion, it is possible that, for example, 1,188 individuals with Type I diabetes would gain 2 years of life while 22,572 individuals with Type II diabetes

[45] RAND, page 28.

[46] This is an absolute value concept which applies to both procedures done and not done. RAND, page 9.

[47] RAND, page 30.

[48] *http://www.cdc.gov/media/pressrel/2008/r080624.htm*, accessed 8–12–08

[49] Based on research that Viscoosy and others have done on the value of a statistical value of life, $50,000 for a year of full quality of life appears to be conservative. We have updated the estimated a statistical life year based on inflation since RAND examined the issue based on the value that HHS has used in a number of regulations.

[50] RAND, page 30.

[51] This is different from RAND's parameter of 0.1, but was confirmed through discussions with the authors.

would gain 6 months of full quality life. We attribute the difference in longevity to the fact that Type I diabetes usually manifests itself in younger persons. Changes made earlier in a person's life will have a longer deterioration curve by about two years than changes made later in a person's life.

When we combine the parameters, we could realize an annual benefit of $237.6 million for Type I diabetes and $1.1286 billion for Type II diabetes already in a plan for a total of $1.3662 billion. We could potentially show an annual benefit for better management of diabetes to be $3.6234 billion ($2.2572 billion from new Type II patients enrolled in disease management + $1.3662 billion from improved disease management of Type I and Type II patients already in a plan).

Finally, we could share RAND's assumption that the diabetes benefit is about two-thirds of the total benefit for improved case management attributable to converting to ICD–10. Under RAND's assumption the total annual benefit for improved disease management would be $5.4351 billion. We assume a phase-in of benefits prior to the fourth year of implementation where 100 percent of the benefit is realized in the fourth year after implementation.

The aforementioned scenario is based upon our interpretation of RAND's scenario that the benefit of improved disease management could conceivably be expected from ICD–10–CM and ICD–10 PCS code sets applied to the sample disease, diabetes. However, although we agree that the potential benefits of disease management could be large, we do not necessarily agree with the calculations used in RAND's theory because we believe they assume much greater benefits than can be directly attributable to the ICD–10 code set alone, such as the development of new and improved diabetes drugs or improved patient outreach, monitoring and communications. RAND also does not take into account disease management benefits from across the full clinical spectrum. For purposes of this analysis, we very conservatively claim a one percent benefit of our total disease management calculations based on RAND's formulas, and solicit feedback from the industry on this assumption.

Therefore, for purposes of this impact analysis, we estimate that the total benefit of improved disease management may equal approximately $582.57 million with a minimum range estimate of $291 million and a maximum estimate of $1,165 million.

f. Better Understanding of Health Conditions and Health Care Outcomes

ICD–10–CM and ICD–10–PCS provide specific diagnosis and treatment information that can improve quality measurements and patient safety, and the evaluation of medical processes and outcomes. ICD–10–PCS has the capability to readily expand and capture new procedures and technologies. For quality improvement programs to effectively result in meaningful clinical outcomes, improved practice management processes that document and measure patient care, and sustain provider investment in services that improve quality of care, the ability to modify or add to a list of treatments, diseases and conditions is essential. The ICD–10 code sets provide a standard coding convention that is flexible, providing unique codes for all substantially different procedures or health conditions and allowing new procedures and diagnoses to be easily incorporated as new codes for both existing and future clinical protocols.

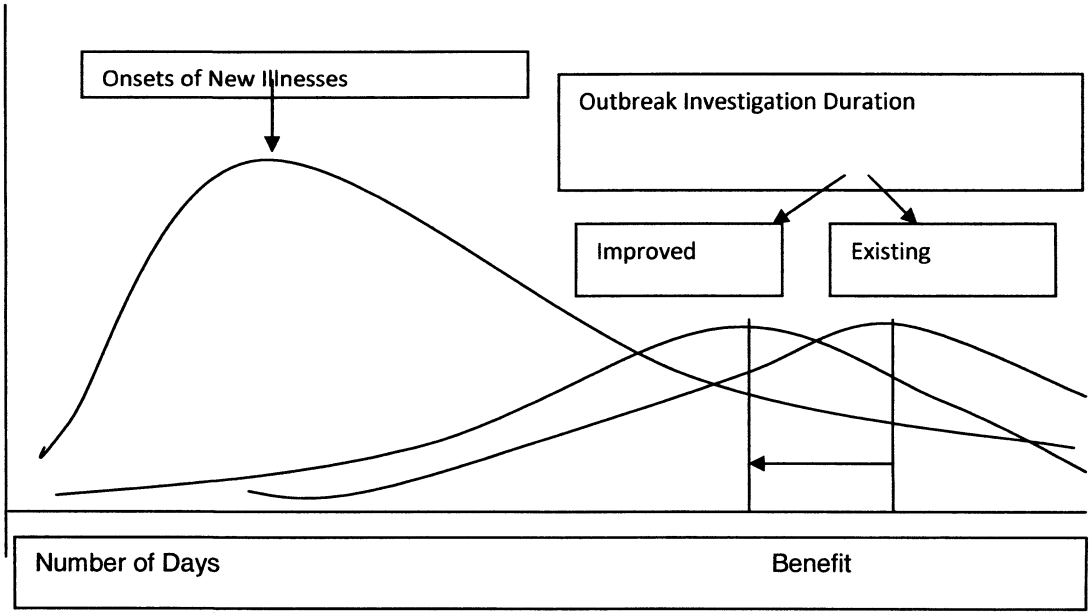
g. Harmonization of Disease Monitoring and Reporting World-Wide

Another benefit we expect will be achieved with the implementation of the ICD–10–CM codes is better coordination of disease outbreak reporting with other countries. Most industrialized countries have adopted the ICD–10 code structure and, with the United State's adoption of the codes, the time to identify and respond to cross-border disease outbreaks will be reduced. We will be able to process public health warnings coming from other countries faster and be able to respond more accurately to the threats because of the greater precision of the coding compared to ICD–9.

Below is a chart that illustrates the reduction in response time we expect to achieve from the implementation of ICD–10–CM codes. After the outbreak of an illness occurs, as represented by the large curve on the left of the chart, there is a reporting lag and a further delay for the processing and analyzing of reports and the mounting of a response. The sooner outbreaks are reported to public health officials and the more accurate the information that is reported, the faster officials can respond. The two smaller curves on the right side of the chart represent the time between outbreak and response under the current coding and the enhanced response time. The shift to the left of the response time represents the benefit in terms of the short response time and outbreak.

The following chart was originally published in an FDA rule, ''Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' It was published in the **Federal Register** on December 9, 2004 (Vol. 69, No. 236; Rules and Regulations 71615) and was adapted for use in this regulation.

Table: 11 Improvement in Response Time to Cross-Border Public Health Warnings of Disease Threats as a Result of ICD-10 Implementation



Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Establishment and Maintenance of Records for Foods

These benefits would expand communication and interoperability capabilities for biosurveillance and disease reporting at an international level. As noted in a recent report, *The Effectiveness of ICD–10–CM in Capturing Public Health Diseases,* ''* * * the use of ICD–10–CM has great implications for our entire nation since public health diseases, which include epidemic and other diseases related to bioterrorism, are generally able to be captured in a more specific way when using the ICD–10–CM system.'' [52] BioSense, CDC's early event detection system, currently uses ICD–9–CM. Improved clinical detail would be a benefit to a national system designed to improve the nation's capabilities for disease detection, monitoring, and real-time health situational awareness.

As noted in the May 2004 NCVHS Workgroup on Quality Report, titled ''Measuring Health Care Quality: Obstacles and Opportunities'', most other industrialized nations have already transitioned to ICD–10, requiring a painstaking crosswalk of United States diagnosis codes to make international comparisons.

However, even with a crosswalk, comparisons are problematic given that changes to ICD–10 which represent a new understanding of disease (such as the myeloproliferative disorders and myelodysplastic syndrome now being recognized as hematologic malignancies which are classified as neoplasms of uncertain behavior in ICD–9–CM) affect data analysis at the State, national and international level.

Because the U.S. does not currently use ICD–10–CM and ICD–10–PCS, there is insufficient data to quantify the results of these benefits. For additional discussion of biosurveillance, refer to section III.

Table 12 below outlines the total estimated benefits as outlined in the above sections. The table shows both the minimum and maximum ranges for each benefit as well as their corresponding primary estimates.

TABLE 12—SUMMARY OF TOTAL ESTIMATED BENEFITS

	Minimum	Maximum	Primary estimate
More accurate payments for new procedures	$121	$1,455	$1,032
Fewer rejected claims	242	3,031	1,015.41
Fewer improper claims	121	1,455	508.22
Better understanding of new procedures	121	1,819	812.54
Improved disease management	291	1,165	582.57

[52] ''The Effectiveness of ICD–10–CM in Capturing Public Health Diseases.'' AHIMA, *Perspectives in Health Information Management 2007* (June 12, 2007), *http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_036019.html*, accessed 8–12–08.

C. Alternatives Considered

As discussed in detail in section VII of the preamble of this proposed rule, we considered a number of options for replacing ICD–9. We considered extending the life of ICD–9–CM by utilizing unassigned codes, use of CPT–4 for coding inpatient hospital procedures, and waiting to adopt ICD–11 as alternatives to the adoption of ICD–10–CM and ICD–10–PCS. We determined that adopting ICD–10–CM and ICD–10–PCS was the only viable alternative that would meet the long-term coding needs of the health care industry.

1. Relation to and Impact on Other HIT Initiatives

Both Federal and private-sector stakeholders prefer synchronization of related Federal HIT initiatives to permit adequate planning, resources, and implementation. Because implementation of ICD–10 is a massive undertaking, these initiatives should be queued up as rationally as possible. Most of the initiatives related to the adoption of ICD–10 involve promulgation of regulations and compliance dates. In this respect, there is minimal flexibility when some regulations may be promulgated and related compliance dates. Under sections 1860D–4(e)(1), 1860D–4(e)(3) and 1860D–4(e)(4)(D) of the Act, we were required to promulgate uniform standards for e-prescribing not later than April 1, 2008. Not later than one year after promulgation of such final standards, prescriptions and other prescription-related information for drugs covered under Medicare Part D and for individuals eligible for Part D benefits must be transmitted only in accordance with such standards. We anticipate that most of this regulatory activity will take place in 2008. At the same time, there are a number of related Departmental and private sector initiatives that will be ongoing during this time period, although specific dates are not available at this time. During the next several years, for instance, we anticipate that the Certification Commission for Healthcare Information Technology (CCHIT) will be completing and updating certification criteria for ambulatory EHRs, inpatient EHRs, and health information networks. CCHIT has already developed certification criteria for ambulatory EHRs and inpatient EHRs and has already begun certifying both types of products. CCHIT has also begun developing certification criteria for networks. Once CCHIT has established the certification criteria, it plans to update them on a yearly basis to align its efforts with the standards harmonization efforts of the Healthcare Information Technology Standards Panel (HITSP).

HITSP seeks to achieve widely accepted and readily implemented consensus-based standards that will enable and support widespread interoperability among health care information technology users, especially as they would interact in a Nationwide Health Information Network (NHIN) for the United States. On October 31, 2006, HITSP presented three sets of ''interoperability specifications'' to the American Health Information Community (AHIC), a Federal advisory committee chartered to make recommendations to the Secretary on methods for accelerating the development and adoption of health information technology. The AHIC considered HITSP's presentation, and after reaching consensus, recommended to the Secretary that he recognize certain interoperability specifications. On March 1, 2007, the Department published a Notice of Availability (72 FR 9339), identifying the recommended specifications, and indicating the Secretary's acceptance and anticipated recognition of the interoperability specifications. In January 2008, following a one-year period of implementation testing, the Secretary announced his formal recognition of HITSP interoperability specifications (*http://www.hitsp.org/government.aspx*, accessed 8–12–08.)

Both CCHIT and HITSP have developed processes that build industry consensus and support voluntary adoption of health information technology standards. By ''recognizing'' interoperability standards, the Secretary is also advancing the adoption of health IT standards within the Federal government and among many of its contractors (See Executive Order 13410—Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs), and for certain entities seeking to donate EHR software and training services in compliance with the Stark EHR Exception and the Anti-Kickback EHR Safe Harbor (See 71 FR 45140 and 71 FR 45110). Finally, trial implementations of the Nationwide Health Information Network (NHIN), including specifications and testing of interoperable health information exchange, are proceeding.

The implementation of ICD–10 will promote the use of HIT and increase the overall value of EHRs. Updating a coding system to a more rigorous and exact coding system such as ICD–10 results in the ability to more accurately understand changes in medical technology, treatment patterns, disease spread, and outcomes of quality measures. The detail and precision of the ICD–10 codes will allow for any necessary updates to quality measures, payment systems, fraud prevention and clinical decision support mechanisms. ICD–10 is already included in the HITSP electronic health record (EHR) use case, and as an administrative standard it will drive change as it will be required for use on all claims.

ICD–10 impacts on HIT initiatives might come in the form of the industry needing time to become comfortable with the new codes, resulting in benefits being reaped 1–2 years after implementation. While there will be resource impacts on other HIT initiatives as a result of the ICD–10 implementation, there will be greater impacts if ICD–10 is delayed and more EHR systems need to be retrofitted.

CMS solicits industry and stakeholder comments on the direct and indirect impacts to current Health Information Technology initiatives.

Tables 13a and b below outline the total estimated benefits and costs as outlined in the above sections. The table illustrates in which years we believe each cost and benefit will be realized.

Table 13a: Estimated Annual Costs for Years 2009-2023 (in millions and adjusted for inflation)

Estimate Costs for Years 2009 - 2023 (in millions)																
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Training																
Full-time Coders/Inpatient	0.00	20.63	103.13	13.75	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	137.51
Part-time Coders/Outpatient	0.00	9.85	78.76	9.85	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	98.50
Code Users	0.00	3.75	30.00	3.75	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	37.50
Physicians	0.00	8.22	65.76	8.22	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	82.20
Productivity Losses																
Coders-- Inpatient	0.00	0.00	8.90	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8.90
Coders--Outpatient	0.00	0.00	8.56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8.56
Physician Practices	0.00	0.00	10.98	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	10.98
Improper and Returned Claims	0.00	0.00	0.00	329.29	164.64	49.39	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	543.29
System Changes																
Providers	20.58	41.16	68.60	6.86	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	137.20
Software Vendors	14.41	28.81	48.02	4.81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	96.05
Payers	24.70	49.39	82.32	8.23	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	164.64
Government	47.09	94.18	156.98	15.70	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	315.00
Total	106.78	255.99	662.01	400.46	164.64	49.39	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1640.33

Table 13b: Estimated Benefits for Years 2009 - 2023 (in millions and adjusted for inflation)

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
More accurate payments for new procedures	0.00	0.00	0.00	0.00	18.30	49.16	61.94	72.85	83.92	95.16	106.58	118.18	129.95	141.91	154.05	1032.00
Fewer Rejected Claims	0.00	0.00	0.00	0.00	25.40	51.21	82.60	104.06	104.90	105.74	106.58	107.43	108.30	109.16	110.03	1015.41
Fewer improper Claims	0.00	0.00	0.00	0.00	13.21	25.60	41.30	52.03	52.45	52.87	53.29	53.72	54.15	54.58	55.02	508.22
Better understanding of new procedures	0.00	0.00	0.00	0.00	12.19	32.77	82.60	83.25	83.92	84.59	85.27	85.95	86.64	87.33	88.03	812.54
Improved Disease Management	0.00	0.00	0.00	0.00	16.57	44.53	56.11	56.56	57.01	57.47	57.93	58.40	58.86	59.33	59.80	582.57
Total	0.00	0.00	0.00	0.00	85.67	203.27	324.55	368.75	382.20	395.83	409.65	423.68	437.90	452.31	466.93	3950.74

Table 14: Net Benefits and Cumulative Net Benefits (in millions and adjusted for inflation)

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Net Benefits	(106.78)	(255.99)	(662.01)	(400.46)	(78.97)	153.88	324.55	368.75	382.20	395.83	409.65	423.68	437.90	452.31	466.93
Cumulative Net Benefits	(106.78)	(362.77)	(1024.8)	(1425.24)	(1504.21)	(1350.33)	(1025.78)	(657.03)	(274.83)	121.00	530.65	954.33	1392.23	1844.54	2311.47

D. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires that the Secretary certify that a proposed regulation will not have a significant economic impact on a substantial number of small entities. In the health care sector, a small entity is one with between $6.5 million and $31.5 million in annual revenues or is a nonprofit organization. For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and States are not included in the definition of a small entity. We have attempted to estimate the number of small entities and provide a general discussion of the effects of the proposed regulation.

Because most medical providers are either nonprofit or meet the SBA's size standard for small business, we treat all medical providers as small entities.

1. Alternatives Considered

As mentioned in section VII of the proposed rule, we considered various policy alternatives to adopting ICD–10–CM and ICD–10–PCS. One alternative that was considered included the use of unassigned codes. Although it may be possible to extend the life of ICD–9–CM by assigning codes to new diagnoses and procedures without regard to the hierarchy of the code set, it does not represent a long-term solution and will only be effective as long as there are empty code slots. Moreover, it does not address the remaining shortcomings of ICD–9–CM such as the critical lack of detail that is required to support evolving business needs and advanced technology.

Another alternative that was considered included the use of CPT–4 for coding hospital inpatient procedures. Both the National Committee on Vital and Health Statistics (NCVHS) and GAO found structural problems and serious flaws with CPT–4 for coding inpatient hospital procedures since the system could not capture all services in all health care settings.

A final alternative that was considered was waiting and adopting ICD–11, which is not a feasible option since the WHO is in their earliest stages of development with the earliest projection of the completion being 2016. However, based on past experience with the development of ICD–10 being several years late, it is anticipated that this date will slip. The U.S version would then need to be developed requiring additional analysis, which could take a minimum of 3–5 years (optimistically). It is not expected that ICD–11 will be available for use in the U.S. until at least 2020.

We considered a number of options for implementing the transition to ICD–10 but rejected them as being too costly and too burdensome. One of the options we considered included phasing in the implementation of the new codes either by geographic region as Canada and Australia did, or by provider/supplier category. We rejected these alternatives because it would require plans, especially national plans and possibly multi-state chain or national providers/suppliers or health care entities that were vertically integrated, to maintain and operate both the ICD–9 and ICD–10 coding systems for an extended period of time. Code users in national payer

plans would have to learn the new ICD–10 codes at the same time work with the old ICD–9 codes, which would increase the chance of errors in payments, create confusion and uncertainty in the providers/supplier community and result in delays in processing claims. We believe the cost of maintaining two systems running concurrently would impose a very significant burden on plans and providers/suppliers.

Another option for implementing the transition to the new coding system is to maintain both the ICD–9 and ICD–10 systems for a period of time. We rejected this alternative for many of the same reasons we rejected phasing in the ICD–10 code sets. Maintaining two systems imposes a significant burden on payers and providers/suppliers as well as creates conditions for increased coding errors and payment delays. In addition, because Medicare updates the ICD codes on October 1 of each year, implementation of any new codes must take place on that date. Given the risks for error and the added costs, there seems to be little benefit to be gained from providing the opportunity for parallel coding systems beyond the October 1 deadline being proposed in this rule.

A third option that was considered and rejected was to delay implementation for small entities. However, because we treat all heath care providers/suppliers as small entities, we did not see any benefit to be gained from delaying implementation of the ICD–10 code sets beyond the four-year implementation period being proposed in the rule. Delaying implementation would only have an adverse effect on implementation of other standards that use the ICD codes. Those standards and the systems built around those standards would either have to be pushed off further into the future or have to be revised and redesigned to accommodate the ICD–10 code sets. The costs of such delays could be substantial. Therefore we rejected this option for ICD–10 implementation.

2. Number of Small Entities

Two hundred nonprofit health care organizations that offer 213 plans are considered small entities because of their nonprofit status. Practices of doctors of osteopathy, podiatry, chiropractors, mental health independent practitioners with annual receipts of less than $6.5 million are considered to be small entities. Solo and group physicians' offices with annual receipts of less than $9 million (97 percent of all physician practices) are also considered small entities, as are clinics. Approximately 92 percent of medical laboratories, 100 percent of dental laboratories and 90 percent of durable medical equipment suppliers are assumed to be small entities as well. The American Medical Billing Association (AMBA) (*http://www.ambanet.net/AMBA.htm*, accessed 8–12–08) lists 97 billing companies on its Web site. It notes that these are the only companies with Web sites. The Statistics of U.S. Businesses data shows that there are 97,556 firms involved in system design and related services (NAICS code 5415) providing software services, data processors, computer facilities management services, computer system design services, custom programming services as well as other computer-related services.

Table 9 above (see section XI.B.6.d) presents the impact of the ICD–10 implementation costs on all entities we anticipate will be affected by the rule. Because we consider all health care provider-suppliers as small entities, Table 9 shows that the proposed rule will not have a significant impact on a substantial number of small health care entities. The following table (Table 15) summarizes the results from Table 9 for inpatient and outpatient providers/suppliers.

TABLE 15—IMPACT ON INPATIENT AND OUTPATIENT PROVIDER-SUPPLIERS

Providers/suppliers	Firms	Revenue-receipts ($ millions)	ICD–10 costs (million $)	% ICD–10 cost of revenue receipts
Inpatient	27,276	801,749	228.55	0.03
Outpatient	635,654	537,417	165.36	0.03

To determine the impact on small insurance carriers, third party administrators and system design and related services firms, we first determined the number of entities that meet the SBA size standard. For insurance carriers and third party administrators, the SBA size standard is annual receipts of $6.5 million. For system design and related services firms, the SBA size standard is annual receipts of $23 million.

Using the Statistics for U.S. Businesses for firm sizes by number of employees for 2005 (the latest year for which the Census Bureau reports payroll), we combined total annual payroll reported for NAICS 524114 and 524292 for a total of $32.5 billion (*http://www.census.gov/epcd/susb/2005/us/US—.HTM*, accessed 8–21–08) Taking the total premium payments made to health insurers reported for 2006 (the latest year for which CMS has insurance premium data) in the National Health Expenditure Report of $723.4 billion (*http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp*, accessed 8–12–08), we divided total insurance premiums by total payroll to arrive at a ratio of annual health insurance receipts to annual payroll of 22.3.

Applying the ratio to the reported annual payroll for the employee size categories and dividing by the number of firms in each category, we found that firms with between 10 and 19 employees had average annual receipts of $8.3 million.

Based on the method for computing annual receipts for firms by the number of employees, we estimate that 71 percent of insurers and third party administrators account for 2.5 percent of annual receipts. Applying this percent to the projected costs of system changes for payers found in Table 13a, the costs to small insurers and third party administrators is expected to be a total of $4 million for the anticipated four-year implementation period. Thus, the annual cost is expected to be approximately $1 million or 0.01 percent of revenues.

We applied the same approach for system design and related computer services firms and used 2006 receipt data from the Statistics of U.S. Businesses Annual Survey for NAICS 5415 in place of the National Health Expenditure data, *http://www.census.gov/svsd/www/services/sas/sas_data/sas54.htm*, accessed 8–12–08). Dividing total annual receipts by total annual payroll, we applied a ratio of 2.4468 to the annual payrolls of the various employee size categories and

found that firms with between 100 and 499 employees had average annual receipts of $27.7 million. Total annual receipts for all small entities equal $107 billion which represents 53.3 percent of total annual receipts for the NAICS category. By comparison, the number of small entities represents 99.3 percent of all firms in this category.

Taking the small entity receipt ratio to total receipts and applying it to the expected ICD–10 implementation costs, we find that the cost to small entities equals $51.5 million over the four year implementation period or $12.9 million per year. As a percent of receipts, this equals 0.1 percent.

As we pointed out in discussing the effects of the total costs on third party administrators and system design computer firms, we do not know how many firms will actually be involved in implementing the ICD–10 coding system. For purposes of the analysis, we assume that all firms reported in the Statistics of U.S. Businesses for the NAICS codes we are examining will be participating in the implementation of the codes. Since it is possible we could be including more firms than will be implementing the codes, our impact estimate on small entities may be understated. To test the sensitivity of the impact of the implementation costs on small firms, we assumed that burden would equal three percent of revenues. HHS policy states that if a rule imposes a burden equal to or greater than three percent of a firm's revenues, it is significant (see: ''Guidance on Proper Consideration of Small Entities in Rulemakings of the U. S. Department of Health and Human Services'' at *http://www.hhs.gov/execsec/smallbus.html*, accessed 8–12–08). We assumed that the small business share of the market would remain constant at 53 percent and that the $12.8 million costs we expect small firms to incur will be distributed equally. Using these assumptions, we computed the amount of small entity revenue such that the ICD–10 small entity share would equal three percent—$429 million. We then calculated the percent of $429 million that is the small entity share of the revenue and multiplied the results by the number of small entities (see Table 16). From this analysis we estimate that if only 389 or fewer small firms provide computer and software services, the burden could be significant.

We note that the regulation would not impose any compliance requirements on system design and related services firms and, while the firms may have to wait for some period of time before they are compensated for their services because of contract agreements, they should eventually be able to pass on some or all of their costs on to their customers. In order to determine if these estimates are accurate, we are specifically requesting comments on our analysis and asking for any data that will help us determine the number and sizes of firms implementing the ICD–10 code sets.

Table 16 below summarizes the impact of the rule on small insurance carriers, third party administrators, and system design and related computer design firms.

TABLE 16—PAYERS AND COMPUTER DESIGN AND RELATED SERVICES

NAICS	Payers and system design and related services	Firms	Small entities	Revenue/ receipts ($ millions)	Small entity receipts (in millions $)	% Small entity receipts of total receipts	Annual ICD–10 costs (in millions)	Small entity share of ICD–10 Costs (in millions $)	% Small entity implementation cost/ revenue receipts
524114, 524292.	Health Insurance Carriers and Third Party Administrators.	4,578	3,449	723,412	18,309	2.53	41.13	1.04	0.01
5415	Computer Systems Design and Related Services.	97,556	96,948	200,695	107,048	53.34	24.13	12.87	0.01

It is evident that the conversion to ICD–10 would have a wide-ranging impact, affecting almost every health entity. At minimum, personnel will have to adjust to the new diagnostic codes when submitting bills. For a small enterprise that does business in a relatively narrow range of services or supplies relies primarily on paper records, the change may be minimal involving no more than a software upgrade for its billing system and new super bill forms. Based on a survey published in the June 18, 2008 *New England Journal of Medicine* (Catherine M. DesRoches, Eric G. Campbell, Sowmya R. Rao, et al.) found that 83 percent of doctors did not have electronic records systems (N Engl J Med 2008;359:50–60). Thus, we expect that the vast majority of physicians and practitioners will need to make relatively small changes in their record billing systems.

In the same survey the authors found that only 4 percent of physicians surveyed had fully functional electronic health records systems and 13 percent had a basic electronic health records system. Of the physicians with fully functioning electronic health records, 28 percent belong to group practices with six or more physicians. Nine percent of physicians with access to electronic health record systems practice in hospitals, clinics, and medical centers. Although the cost to transition to the ICD–10-CM codes will be more costly for providers/suppliers with electronic health records systems, the data suggests that large practices and hospitals and medical centers have invested in the sophisticated record systems rather than the average medical practice.

Based upon the previously cited survey, we assume that in many small provider practices, electronic health record systems likely are not used. Some may use practice management systems (most likely for billing purposes) and these will need to be updated. However, the costs for these updates can be attributed to the implementation of Version 5010, and not to ICD–10. Very small provider practices without practice management systems likely use only paper. In these instances, there will be minimal costs, such as revision to their paper records and the updating of their printed super bills. We invite industry and stakeholder comment regarding these assumptions.

At the other extreme are large teaching hospitals and health plans that will not only have to transition to the new diagnostic codes, but also to the new procedure codes. The changes entailed for such large organizations may involve the reconfiguration of entire data systems that will require

hundreds of staff hours in addition to training time and lost productivity. Although the previous analysis indicates that the overall impact on the health care sector of the economy will be very small, we acknowledge that these entities may incur a significant economic impact. However, we believe these organizations comprise a small minority of the total number of health care entities. We solicit industry and stakeholder input on this issue.

To further illustrate the impact we anticipate the rule will have, we developed a scenario for a typical community hospital in the Mid-West. The data for this illustration is drawn from the American Hospital Directory (*http://www.AHD.com*). While based on an actual hospital in a mid-western state, the data has been altered to make calculations simpler. The hospital has 100 beds, 4,000 discharges annually, and gross revenues of $200 million. Using the factors presented in the impact analysis, we estimated training costs (including the cost of the actual training as well as lost time away from the job), productivity loss for the first 6 months resulting from becoming familiar with the diagnostic and procedure codes, and the cost of system changes. For our scenario, we assumed that the hospital employs three full-time coders who will require eight hours of training at $500 per coder for $1,500 ($500 × 3). While they are in training, the hospital will have to substitute other staff either by hiring temporary coders if possible or shifting staff. The estimated cost at $50 per hour is $1,200 (8 hours × 3 staff × $50 per hour).

In estimating the productivity loss, we are only looking at the initial 6 months after implementation. Therefore we divided the annual number of discharges of 4,000 by 2 to equal 2,000. We assume that 3/4 of the discharges are surgical, giving us 1,500 discharges requiring use of PCS codes. Dividing this by 6 months yields an average monthly discharge rate of 250.

We perform a similar calculation for outpatient claims. Of the 13,000 outpatient claims, the monthly average is 1,083 (we do not distinguish between medical and surgical outpatient claims).

Applying the 1.7 extra minutes per discharge, we estimate it would take an extra 425 minutes (1.7 × 250) to code the discharges in the first month. At $50 per hour, the cost per minute is $0.83 ($50/60 minutes) and the cost per claim is $1.41 ($0.83 × 1.7). For the first month, the productivity loss for inpatient coding is $353 ($1.41 × 250). Assuming for simplicity's sake that the resumption of productivity over the 6-month period would increase in a straight line, we divide the $353 by six to come up with $59. We reduce the productivity loss by this amount each month through the sixth month. The total loss for the 6-month period is $1,233.

We apply the same method to determine the outpatient productivity loss. Based on our assumption that outpatient claims will require one-hundredth of the time for hospital inpatient claims, we applying the .017 extra minutes per claim, we estimate it would take an extra 18.41 minutes (0.017 × 1083) to code the discharges in the first month. At $50 per hour, the cost per minute is $0.83 ($50/60 minutes) and the cost per claim is $0.014 ($0.83 × 0.017). For the first month, the productivity loss for inpatient coding is $15.28 ($0.014 × 1083). Assuming for simplicity sake that the resumption of productivity over the 6-month period would increase in a straight line, we divide the $15.28 by six; to come up with $2.55. We reduce the productivity loss by this amount each month through the sixth month. Thus the total loss for the first 6 months will equal $53.

In estimating the cost of system changes and software upgrades, we deliberately chose a value that we think overstates the cost. We assumed that hospital will have to spend $300,000 on its data infrastructure to accommodate the new codes. Summing the training costs, productivity losses, and system upgrades, we estimate the total cost to the hospital will equal approximately $303,990. Finally, in order to determine the percent of the hospital's revenue that would be diverted to funding the conversion to the ICD–10 we compared the estimated cost associated with the conversion to ICD–10 to the total hospital revenue of $200 million. The costs amount to 0.15 percent of the hospital's annual revenues.

We note that although the impact in our scenario of 0.15 percent is significantly larger than the estimated impact of 0.03 percent for inpatient facilities in the Table 15 above, it is still significantly below the threshold the Department considers a significant economic impact. As expressed in the Department guidance on conducting regulatory flexibility analyses, the threshold for an economic impact to be considered significant is 3 percent to 5 percent of either receipts or costs. As is clear from the analysis, the impact does not come close to the threshold. Thus based on the foregoing analysis, we conclude that some health care providers or suppliers may encounter significant burdens in the course of converting to the ICD–10 codes. However, we are of the opinion that, for most providers and suppliers, payers and computer firms involved in facilitating the transition, the costs will be relatively small.

3. Conclusion

Based on the foregoing analysis, we could certify that this proposed regulation would not have a significant economic impact on a substantial number of small entities. However because of the substantial uncertainty in the data and our assumptions we invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the various categories of entities affected by the rule.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a–4.pdf*) (accessed 8–12–08), in Table 12 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. This table provides our best estimate of the costs and benefits associated with the implementation of ICD–10–CM and ICD–10–PCS in 2011 as HIPAA standard code sets to replace ICD–9–CM. All exclassified as implementation for HIPAA covered entities.

TABLE 17—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2009 TO FY 2023

[In millions]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
Benefits				
Annualized Monetized benefits:				
7% Discount	$212.1	$72.3	$233.6	RIA.
3% Discount	241.0	82.2	265.4	RIA.
Qualitative (un-quantified) benefits	Improved biosurveillance and global disease management.			RIA.
Costs				
Annualized Monetized costs:				
7% Discount	$144.9	$40.1	$159.4	RIA.
3% Discount	124.8	34.4	137.3	RIA.
Qualitative (un-quantified) costs	None	None	None	
Transfers				
Annualized monetized transfers: ''on budget''	N/A	N/A	N/A	
From whom to whom?	N/A	N/A	N/A	
Annualized monetized transfers: ''off-budget''	N/A	N/A	N/A	
From whom to whom?	N/A	N/A	N/A	

F. Conclusion

Because ICD–9 is the official system of assigning codes to medical diagnoses and procedures associated with hospital and ambulatory utilization, the changeover to ICD–10 codes will have a major impact on the entire health care industry. This transition is needed due to the space and granularity deficiencies inherent in the almost three-decade-old ICD–9 code set, and the increased procedure and diagnosis detail that ICD–10 offers, allowing for more accurate payment of claims.

For hospitals, ambulatory centers, physician offices, and health plans, this transition will be multifaceted, but once adopted, ICD–10 would allow for better coding of complex conditions and procedures as well as a more uniform measure of reimbursement. Providers and payers are likely to need a cross-walk of ICD–9 codes to ICD–10 codes in the beginning of the transition, but as our analysis has shown, in the long-term, the benefits of ICD–10 outweigh its costs.

This impact analysis references two reports that outline the costs and benefits of transitioning from ICD–9 to ICD–10. These reports include ''The Costs and Benefits of Moving to the ICD–10 Code Sets'' by the RAND Corporation, and ''Replacing ICD–9–CM with ICD–10–CM and ICD–10–PCS Challenges, Estimated Costs, and Potential Benefits'' by the Robert E. Nolan Company. For purposes of this impact analysis, we also reference field studies and interviews done by AHIMA, which detail first-hand accounts of the benefits of using the ICD–10 code sets.

If we do not implement ICD–10 codes, we could continue to use ICD–9 codes; however, as mentioned in previous sections of this impact analysis, ICD–9 codes do not capture new technologically-advanced procedures, there would be an increased need to add new codes in illogical locations which would cause more confusion and inaccuracy when assigning codes, and there would possibly be improper payments for inaccurate diagnoses and procedures.

Because of the considerable uncertainty in the data and our assumptions we invite public comments regarding whether this proposed regulation would have a significant economic impact on a substantial number of small entities. We request any additional data that would help us determine more accurately the impact on the various categories of entities affected by the rule.

We have considered the alternatives specified in section XI of the preamble of this proposed rule. We welcome comments on ways to lessen any burdens from our proposal, on alternatives that might be more effective or less costly, and/or any other improvements we can make before issuing a final rule.

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

List of Subjects in 45 CFR Part 162

Administrative practice and procedures, Electronic transactions, Health facilities, Health Insurance, Hospitals, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in this preamble, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter C, part 162 as follows:

PART 162—ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

Authority: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–1320d–8), as added by sec. 262 of Public Law 104–191, 110 Stat. 2021–2031, and sec. 264 of Public Law 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)).

2. Section 162.1002 is amended by revising paragraph (b) introductory text and adding paragraph (c) to read as follows.

§ 162.1002 Medical data code sets.

* * * * *

(b) For the period on and after October 16, 2003 through September 30, 2011:

* * * * *

(c) For the period on and after October 1, 2011:

(1) The code sets specified in paragraphs (a)(4), (a)(5), (b)(2), and (b)(3) of this section.

(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) (including The Official ICD–10–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(3) International Classification of Diseases, 10th Revision, Procedure Classification System (ICD–10–PCS) (including The Official ICD–10–PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

(i) Prevention.

(ii) Diagnosis.

(iii) Treatment.

(iv) Management.

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Approved: March 12, 2008.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on August 15, 2008.

[FR Doc. E8–19298 Filed 8–15–08; 3:55 pm]

BILLING CODE 4120–01–P

Federal Register

Friday,
August 22, 2008

Part IV

Department of Justice

Antitrust Division

United States v. UnitedHealth Group Incorporated; Response to Public Comments on the Proposed Final Judgment; Notice

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. UnitedHealth Group Incorporated; Response to Public Comments on the Proposed Final Judgment

Pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), the United States hereby publishes the public comments received on the proposed Final Judgment in *United States* v. *UnitedHealth Group Incorporated,* Civil Action No. 1:08–cv–322, and the response to the comments. On February 25, 2008, the United States filed a Complaint alleging that the merger of UnitedHealth Group Incorporated (''United'') and Sierra Health Services, Inc. (''Sierra'') violated Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed on February 25, 2008, requires the combined company to divest United's individual Medicare Advantage line of business in the Las Vegas, Nevada area. Public comment was invited within the statutory 60-day comment period. Copies of the Complaint, proposed Final Judgment, Competitive Impact Statement, Public Comments, the United States' Response to the Comments, and other papers are currently available for inspection in Department of Justice, Antitrust Division, Antitrust Documents Group, 450 5th Street, NW., Suite 1010, Washington, DC 20530, telephone: (202) 514–2481 and the Office of the Clerk of the United States District Court for the District of Columbia, 333 Constitution Avenue, NW., Washington, DC 20001.

Copies of any of these materials may be obtained upon request and payment of a copying fee.

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

In the matter of: United States District Court for the District of Columbia; United States of America, Plaintiff, v. UnitedHealth Group Incorporated and Sierra Health Services, Inc., Defendants.

[Case No. 1:08–cv–322–ESH]

Response of Plaintiff United States to Public Comments

Pursuant to the requirements of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. 16(b)–(h), the United States hereby files the four public comments that the United States received concerning the proposed Final Judgment in this case and the United States' response to those comments. The United States will move the Court for entry of the proposed Final Judgment after the comments and this Response have been published in the **Federal Register**, pursuant to 15 U.S.C. 16(d).

On February 25, 2008, the United States filed the Complaint in this matter alleging that the proposed merger of UnitedHealth Group Incorporated (''United'') and Sierra Health Services, Inc. (''Sierra'') would violate Section 7 of the Clayton Act, 15 U.S.C. 18. Simultaneously with the filing of the Complaint, the United States filed a proposed Final Judgment and a Hold Separate and Asset Preservation Stipulation and Order (''Stipulation'') signed by the United States and Defendants consenting to the entry of the proposed Final Judgment after compliance with the requirements of the Tunney Act.[1] Pursuant to those requirements, the United States filed a Competitive Impact Statement (''CIS'') in this Court on February 25, 2008; published the proposed Final Judgment and CIS in the **Federal Register** on March 10, 2008, see 73 FR 12762 (2008); and published summaries of the terms of the proposed Final Judgment and CIS, together with directions for the submission of written comments relating to the proposed Final Judgment, in the *Washington Post* for seven days beginning on March 16, 2008 and ending on March 22, 2008, and in the *Las Vegas Review-Journal* for seven days beginning on March 8, 2008 and ending on March 14, 2008. The 60-day period for public comments ended on May 15, 2008, and the United States received the four comments described below and attached hereto.

I. The United States' Investigation and the Proposed Final Judgment

On March 11, 2007, United and Sierra entered into an agreement, whereby United agreed to acquire all outstanding shares of Sierra. Over the next eleven months, the United States Department of Justice (the ''Department'') conducted an extensive, detailed investigation into the competitive effects of the proposed transaction. As part of this investigation, the Department obtained substantial documents and information from the merging parties and issued numerous Civil Investigative Demands to third parties. In response, the Department received and considered more than 2.5 million pages of material. The Department conducted approximately 150 interviews with customers, hospitals and physician groups, insurance companies, and other individuals with knowledge of the industry.

After conducting a detailed analysis of the acquisition, the Department concluded that the combination of United and Sierra likely would substantially lessen competition in the Las Vegas, Nevada area (consisting of Clark and Nye Counties, Nevada) in a product market no broader than the sale of Medicare Advantage health-insurance plans to senior citizens and other Medicare-eligible individuals. As defined by federal law, Medicare Advantage plans consist of Medicare Advantage health maintenance organization plans (''MA–HMO''), Medicare Advantage preferred provider organization plans (''MA–PPO''), and Medicare Advantage private fee-for-service plans (''MA–PFFS''). *See* 42 U.S.C. 1395w–21(a)(2). United and Sierra together would have accounted for approximately 94 percent of the total enrollment in Medicare Advantage plans in the Las Vegas area, which accounts for approximately $840 million in annual commerce. United markets and sells its Medicare Advantage products under the Secure Horizons and AARP brands. Sierra markets and sells its Medicare Advantage products under the Senior Dimensions, Sierra Spectrum, Sierra Nevada Spectrum, and Sierra Optima Select brands.

As more fully explained in the CIS, the Stipulation and proposed Final Judgment in this case are designed to preserve competition in the sale of Medicare Advantage health-insurance plans in the Las Vegas area by requiring United to divest its individual Medicare Advantage line of business in the Las Vegas area. The Stipulation and proposed Final Judgment also require United to take several steps to assist the acquirer in providing prompt and effective competition in the Medicare Advantage market, including assisting the acquirer to enter into agreements that will allow members of United's Medicare Advantage plans to have continued access to substantially all of United's provider network of physicians, hospitals, ancillary service providers, and other health care providers on terms no less favorable than United's existing agreements. United must also provide transition support services for medical-claims

[1] The merger closed on February 25, 2008. In keeping with the United States' standard practice, neither the Stipulation nor the proposed Final Judgment prohibited closing the merger. *See* ABA Section of Antitrust Law, *Antitrust Law Developments* 406 (6th ed. 2007) (noting that ''[t]he Federal Trade Commission (as well as the Department of Justice) generally will permit the underlying transaction to close during the notice and comment period''). Such a prohibition could interfere with many time-sensitive deals and prevent or delay the realization of substantial efficiencies.

processing, appeals and grievances, call-center support, enrollment and eligibility services, access to form templates, pharmacy services, disease management, Medicare risk-adjustment services, quality-assurance services, and such other services as are reasonably necessary for the acquirer to operate the Divestiture Assets.

On February 25, 2008, United and Humana Health Plan Inc. (''Humana'') signed an agreement providing for Humana to purchase United's Las Vegas Medicare Advantage line of business for approximately $185 million. After receiving approval from the Centers for Medicare and Medicaid Services (''CMS'') and the Nevada Division of Insurance, Humana completed the acquisition of United's Las Vegas Medicare Advantage line of business on May 1, 2008. In the Department's judgment, the divestiture of United's Las Vegas Medicare Advantage line of business to Humana, along with the other requirements contained in the Stipulation and proposed Final Judgment, are sufficient to eliminate the anticompetitive effects identified in the Complaint.

II. Standard of Judicial Review

Upon the publication of the Comment and this Response, the United States will have fully complied with the Tunney Act and will move for entry of the proposed Final Judgment as being ''in the public interest'' 15 U.S.C. 16(e)(l), as amended.

The Tunney Act states that, in making that determination, the Court shall consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A)–(B); *see generally United States* v. *AT&T Inc.,* 541 F. Supp. 2d 2, 6 n.3 (D.D.C. 2008) (listing factors that the Court must consider when making the public-interest determination); *United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1, 11 (D.D.C. 2007) (concluding that the 2004 amendments to the Tunney Act ''effected minimal changes'' to scope of review under the Tunney Act, leaving review ''sharply proscribed by precedent and the nature of Tunney Act proceedings'').[2]

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA, a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1458–62 (D.C. Cir. 1995). With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (citing *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also* Microsoft, 56 F.3d at 1460–62. Courts have held that:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is *''within the reaches of the public interest.''* More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted). *Cf. BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest' '').

The government is entitled to broad discretion to settle with defendants within the reaches of the public interest. *AT&T Inc.,* 541 F. Supp. 2d at 6. In making its public-interest determination, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns, 489* F. Supp. 2d at 17; see also *Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Court approval of a consent decree requires a standard more flexible and less strict than that appropriate to court adoption of a litigated decree following a finding of liability. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.' '' *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom. Maryland* v. *United States,* 460 U.S. 1001 (1983); *see also United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, rather than to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459. Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Id.* at 1459–60. As this Court recently confirmed in *SBC Communications,*

[2] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for courts to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004), *with* 15 U.S.C. § 16(e)(1) (2006).

courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' *SBC Commc'ns,* 489 F. Supp. 2d at 15.

In its 2004 amendments to the Tunney Act, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2). The amendments codified what Congress intended when it passed the Tunney Act in 1974, as Senator Tunney then explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney). Rather, the procedure for the public-interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11.[3]

III. Summary of Public Comments and the United States' Response

During the 60-day comment period, the United States received comments from the Service Employees International Union Local 1107 (the ''SEIU comment''), the American Medical Association, Nevada State Medical Association, and the Clark County Medical Society (collectively, the ''AMA comment''), the Honorable Nydia M. Velazquez, Chairwoman, United States House of Representatives Committee on Small Business (the ''Velazquez comment''), and the Honorable Chris Giunchigliani, Commissioner, Board of Commissioners—Clark County, Nevada (the ''Giunchigliani comment''). Those comments are attached to this Response.

After reviewing the comments, the United States has determined that the proposed Final Judgment remains in the public interest. The commenters raise two main concerns: (A) that the United States should have alleged and remedied harm to competition in additional product markets other than the Medicare Advantage market alleged in the United States' Complaint and (B) that the proposed Final Judgment does not adequately remedy the harms to competition alleged in the Complaint. The United States addresses these concerns below.

A. Comments That the United States Should Have Alleged and Remedied Additional Competitive Concerns

1. Summary of Comments

Each of the commenters argue that the United States should have alleged and remedied competitive concerns that are not addressed in the Complaint in this matter. They argue that the United States should have pursued a case of harm to competition in a commercial health-insurance market in Clark County, Nevada. (AMA comment at 12; SEIU comment at 4; Velazquez comment at 3; Giunchigliani comment at 1–2). The commenters also express concern that the United-Sierra merger will harm competition in the sale of various types of commercial health insurance, such as the provision of HMO policies, HMO and PPO policies, and the provision of commercial insurance to employers with 50 or fewer employees. (AMA comment at 12; SEIU comment at 4; Velazquez comment at 4; Giunchigliani comment at 1).

The AMA and Velazquez also argue that the United States should have alleged that the transaction would harm physicians and sought an appropriate remedy. They maintain that the merged company will control a sufficient share of the purchases for physicians services in Clark County such that the merged company will be able to reduce payments to physicians below competitive levels. (AMA comment at 5; Velazquez comment at 4). Similarly, the SEIU argues that the merged company will control a sufficient share of purchases of hospital services such that the merged company will be able unilaterally to reduce reimbursement rates to hospitals. (SEIU comment at 4). The SEIU argues that such lower reimbursement rates to hospitals will result in higher patient-to-nurse ratios and place patient safety and quality of care in jeopardy. (SEIU comment at 3–4).

2. The United States' Response

The comments that the United States should have alleged harm to competition for the sale of various types of health insurance or for the purchase of physician or hospital services, which are not addressed in the Complaint, are outside the scope of this APPA proceeding. The Department's decision to allege a harm in a specific market is based on a case-by-case analysis that varies depending on the particular circumstances of each product and geographic market The Department investigated the transaction's potential competitive effects on each of the types of health insurance identified by the commentators, and on the purchase of physician and hospital services, and concluded that it should not allege harm in these markets. As explained by this Court, in a Tunney Act proceeding, the district court should not second-guess the prosecutorial decisions of the Department regarding the nature of the claims brought in the first instance; ''rather, the court is to compare the complaint filed by the United States with the proposed consent decree and determine whether the proposed decree clearly and effectively addresses the [anticompetitive harms initially identified.'' *United States* v. *Thomson Corp.,* 949 F. Supp 907, 913 (D.D.C. 1996); *accord, Microsoft,* 56 F.3d at 1459 (in APPA proceeding, ''district court is not empowered to review the actions or behavior of the Department of Justice; the court is only authorized to review the decree itself''); *BNS,* 858 F.2d at 462–63 (''the APPA does not authorize a district court to base its public interest determination on antitrust concerns in markets other than those alleged in the government's complaint''). This court has held that ''a district court is not permitted to ''reach beyond the complaint to evaluate claims that the government did not make and to inquire as to why they were not made.' '' *SBC Commc'ns,* 489 F. Supp. 2d at 14 (quoting *Microsoft,* 56 F.3d at 1459) (emphasis in original). Nor does the fact that the State of Nevada obtained terms of settlement different from those obtained by the United States alter the ordinary Tunney Act standard of review.

The AMA's contention that the 2004 Amendments to the Tunney Act overruled precedent in this court and require a more extensive review of the United States' exercise of its prosecutorial judgment conflicts with this Court's holding in *SBC Communications, supra.* (AMA

[3] *See United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); *United States* v. *Mid-Am. Dairymen, Inc.,* 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980 (W.D. Mo. 1977) (''Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.''); S. Rep. No. 93–298, 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

comment at 4). In *SBC Communications,* this Court held that ''a close reading of the law demonstrates that the 2004 amendments effected minimal changes, and that this Court's scope of review remains sharply proscribed by precedent and the nature of [APPA] proceedings.'' SBC *Commc'ns,* 489 F. Supp. 2d at 11. This Court continued that because ''review [under the 2004 amendments] is focused on the 'judgment,' it again appears that the Court cannot go beyond the scope of the complaint.'' Id. The 2004 amendments to the APPA, as interpreted and applied by this Court in *SBC Communications,* require the Court to evaluate the effect of the ''judgment upon competition'' in a Medicare Advantage market in the Las Vegas area. 15 U.S.C.16(e)(1)(b). Because the United States did not allege that the United's acquisition of Sierra would cause harm in additional markets, it is not appropriate for the Court to seek to determine whether the acquisition will cause anticompetitive harm in such markets.

B. Comment That the Proposed Final Judgment Does Not Adequately Address the Harms to Competition Alleged in the Complaint

1. Summary of Comment

The AMA states that the remedies in the proposed Final Judgment are inadequate to maintain competition in the sale of Medicare Advantage health-insurance plans in the Las Vegas area. (AMA comment at 13). The AMA argues in its comment that the proposed Final Judgment should include five additional remedies: (1) A permanent injunction on United's use of ''most-favored-nations'' clauses in healthcare-provider contracts; (2) a permanent injunction on United's use of ''all-products'' clauses in healthcare-provider contracts; (3) a divestiture of United's commercial health-insurance business in Clark County; (4) a requirement that United convey the use of certain trademarks to the acquirer of the Medicare Advantage line of business for at least five years; and (5) the immediate use of a monitoring trustee to ensure compliance with the proposed Final Judgment. (AMA comment at 13–15).

2. The United States' Response

The additional remedies proposed by the AMA are not necessary to ensure that competition will remain in the market alleged in the Complaint. Rather, the proposed Final Judgment is in the public interest because it is properly designed to eliminate the anticompetitive effects alleged in the Complaint. First, the proposed Final Judgment requires United to divest its entire individual Medicare Advantage line of business in the Las Vegas area to an acquirer approved by the United States and on terms acceptable to the United States. This line of business covers approximately 25,800 individual Medicare Advantage beneficiaries. As described in Section IV of the proposed Final Judgment, United is required to divest all tangible and intangible assets dedicated to the administration, operation, selling, and marketing of its Medicare Advantage plans to individuals in the Las Vegas area (''the Divestiture Assets''), including all of United's rights and obligations under the relevant United contracts with CMS. Thus, the acquirer will have the benefit of entering the Medicare Advantage market with United's entire individual Medicare Advantage line of business.

Second, the Stipulation and Sections IV(A) and (B) of the proposed Final Judgment required United to divest the Divestiture Assets within the shortest time period reasonable under the circumstances. A quick divestiture has the benefits of maintaining competition that would otherwise be lost in the acquisition and reducing the possibility of dissipation of the value of the assets while the sale is pending. Per these requirements, United divested the Divestiture Assets to Humana on May 1, 2008.

Third, the divestiture eliminates the anticompetitive effects of the merger by requiring United to divest the Divestiture Assets to an acquirer that can compete vigorously with the merged United-Sierra. The United States approved Humana as the acquirer of the Divestiture Assets because Humana is well positioned to be a strong competitor in the Medicare Advantage market in the Las Vegas area. Humana is an established health-insurance competitor with total annual revenue of $26 billion and a market capitalization of $8.3 billion. Humana is the second largest provider of Medicare Advantage plans in the nation after United. The company has 1.27 million Medicare Advantage enrollees nationwide. In the United States' judgment, Humana has the intent and capability (including the necessary managerial, operational, technical, and financial capability) to compete effectively in the sale of Medicare Advantage products, and the asset purchase agreements between United and Humana do not give United the ability to interfere with Humana's ability to compete effectively.

Fourth, the proposed Final Judgment requires Defendants to assist the acquirer in providing prompt and effective competition in the Medicare Advantage market and uninterrupted care to subscribers of United's Medicare Advantage plans by mandating that the Defendants adhere to the following requirements:

- Section IV(F) requires the Defendants to assist the acquirer to enter into an agreement with HealthCare Partners, LLC (''HealthCare Partners'') that will allow members of United's Medicare Advantage plans to have continued access to substantially all of United's provider network of physicians, hospitals, ancillary service providers, and other health care providers on terms no less favorable than United's pre-existing agreement with HealthCare Partners.
- Section IV(J) requires that, at the acquirer's option, and subject to approval by the United States, Defendants provide transition support services for medical claims processing, appeals and grievances, call-center support, enrollment and eligibility services, access to form templates, pharmacy services, disease management, Medicare risk-adjustment services, quality-assurance services, and such other transition services that are reasonably necessary for the acquirer to operate the Divestiture Assets.
- Section IV(G) of the proposed Final Judgment prohibits United, until March 31, 2010, from entering into agreements with healthcare providers who, prior to the transaction, participated in United's Medicare Advantage network, but did not participate in Sierra's.
- Sections IV(F) and (G) collectively ensure that Humana, but not the Defendants, will have access to these healthcare providers, which places Humana in the same competitive position with respect to the merged company as United was in with respect to Sierra prior to the merger of United and Sierra.
- Section IV(H) prohibits United from using the AARP brand for any of its individual Medicare Advantage plans in the Las Vegas area until March 31, 2009, and from using the SecureHorizons brands for any individual Medicare Advantage plans in the Las Vegas area until March 31, 2010. The Department has determined that Section IV(H) will give Humana sufficient time to establish its own brand in the Las Vegas area so that it can effectively compete for the provision of Medicare Advantage plans and reduce beneficiary confusion as to which company operates the Medicare Advantage plan in which the beneficiary is enrolled.

In short, the United States has determined that the remedies in the proposed Final Judgment are sufficient to allow Humana to be an effective

competitor and maintain competition in the Las Vegas Medicare Advantage market. As the United States now explains, the additional remedies that the AMA suggests are not needed to preserve the public interest.

a. Most-Favored-Nations Clauses

The AMA states that the proposed Final Judgment should permanently enjoin United from using ''most-favored-nations'' (''MFN'') clauses in its contracts with healthcare-providers. (AMA comment at 13). As explained in the affidavit of Professor David Dranove, submitted by the AMA, an MFN clause would require a healthcare provider to offer United rates no less favorable than those offered to other insurers. (AMA comment, Attachment A at 8.) MFNs may be anticompetitive or procompetitive, depending on the circumstances. Federal Trade Comm'n & U.S. Dept. of Justice, *Improving Health Care: A Dose of Competition* (Jul. 2004), ch. 6, p. 20, available at *http://www.usdoj.gov/atr/public/health_care/204694.htm.* MFN clauses may harm competition by, for example, discouraging healthcare providers from aggressively discounting to competing insurers who might be seeking to enter or expand in a market. *Id.*

It is not necessary to prohibit United from using MFN clauses to ensure that Humana can compete and maintain the premerger level of competition in Medicare Advantage plans. Pursuant to Section IV(F) of the proposed Final Judgment, on February 29, 2008, Humana entered into an agreement that gives Humana access to United's existing provider network of physicians, hospitals, ancillary service providers, and other healthcare providers on comparable terms to those enjoyed by United at the time of the acquisition. Accordingly, United could not use MFN clauses to attempt to prevent Humana from competing in the Medicare Advantage market. Of course, the United States remains free to challenge arty anticompetitive conduct of United, including MFN clauses, that the United States determines harm competition.

b. All-products Clauses

The AMA states that the proposed Final Judgment should permanently enjoin United's use of ''all-products'' clauses in healthcare-provider contracts. (AMA comment at 13.) An all products clause is a contractual provision that requires a physician or other healthcare provider to agree to participate in the networks for every one of a health-insurance company's products (e.g., commercial health insurance and Medicare Advantage) as a condition for participating in the network of any one of that health-insurance company's products.

The AMA does not make clear how a prohibition on United's use of all-products clauses would help maintain competition in a Medicare Advantage market. (AMA comment at 13.) The AMA comment refers to the affidavit of Professor David Dranove, submitted by the AMA, for an explanation of how all-products clauses can be anticompetitive. (AMA comment, Attachment A at 8.) Although Professor Dranove states in his affidavit that the proposed Final Judgment should prohibit all-products clauses to remedy harm in a market for the purchase of physician services, the Complaint did not allege or identify competitive harm in such a market. (Attachment A at 8.) To the extent that the AMA advocates a prohibition on all-products clauses to remedy harm in a market for the purchase of physician services, such remedies are outside the scope of this APPA proceeding as discussed in Section III.A. of this Response.

c. United's Commercial Health-insurance Business in Clark County

The AMA argues that the proposed Final Judgment should require United to divest its commercial health-insurance business in the Las Vegas area in addition to United's Medicare Advantage line of business because a Medicare Advantage business operating without a commercial component ''faces a significant risk of failure.'' (AMA comment at 13.) The AMA asserts that ''[t]here are significant economies of scope and scale that exist when both commercial and Medicare Advantage businesses are combined'' Id. The AMA, however, does not identify what these economies of scope and scale are nor why their absence creates a risk of failure.

The United States has considered this issue and concluded that Humana has the resources needed to effectively compete for the provision of Medicare Advantage plans in the Las Vegas area. Further, even assuming that there are benefits to providing both commercial and Medicare Advantage products, Section IV(F) of the proposed Final Judgment addresses this concern by ensuring that Humana has access to United's existing healthcare provider network on terms no less favorable than United's premerger terms. That provision and the other provisions of the proposed Final Judgment ensure that Humana will have a cost structure similar to United's premerger cost structure and be an effective competitor that maintains competition in the Las Vegas Medicare Advantage market.

d. Use of Certain Trademarks

The AMA argues that the acquirer of the Divestiture Assets should have use of certain United trademarks (AMA comment at 13–14). Section IV(H) of the proposed Final Judgment prohibits United from using the AARP brand for any of its individual Medicare Advantage plans in the Las Vegas area until March 31, 2009, and from using the SecureHorizons brands for any individual Medicare Advantage plans in the Las Vegas area until March 31, 2010. The AMA argues that the United States should extend these provisions to last at least five years because ''trademarks are of particular importance to continue to secure customer loyalty.'' (AMA comment at 13–14.)

The AMA, however, does not provide any facts to support its assertion that a longer prohibition period on United's use of the AARP and SecurdHorizons brands is necessary to allow Humana to be an effective competitor and maintain competition in the Las Vegas Medicare Advantage market. In the United States' judgment based on a review of the terms for the sale of the Divestiture Assets, its assessment of Humana's capabilities, and its investigation of the Las Vegas Medicare Advantage market, the brand prohibitions in the proposed Final Judgment are reasonable in light of their intended purpose—to give Humana time to establish its own brand in the Las Vegas area and reduce beneficiary confusion as to which company operates the plan in which the beneficiary is enrolled. *See SBC Commc'ns,* 489 F Supp. 2d at 17 (a district court ''must accord deference to the government's predictions about the efficacy of its remedies'').

e. Use of a Monitoring Trustee

The AMA argues that the proposed Final Judgment should require the immediate use of a monitoring trustee to ensure United's compliance with the proposed Final Judgment (AMA comment at 15). Section V of the proposed Final Judgment allows the United States, in its sole discretion and subject to approval by the Court, to appoint a monitoring trustee that would have the power to monitor Defendants' compliance with the terms of the proposed Final Judgment. Section V(H) of the proposed Final Judgment provides that, if a monitoring trustee is appointed, it shall serve until United has divested the Divestiture Assets and any agreements for transition support services have expired.

In the United States' judgment, the immediate use of a monitoring trustee is not necessary to ensure United's compliance with the proposed Final Judgment for at least three reasons. First, United has already complied with many of the provisions of the proposed Final Judgment. United has completed the divestiture of the Divestiture Assets and assisted Humana in entering into an agreement with HealthCare Partners that gives Humana access to healthcare providers on terms no less favorable than United's pre-existing agreement with HealthCare Partners. In addition, Humana and United have entered into a transition services agreement as contemplated by Section IV(J) of the Final Judgment. Second, the United States has reviewed the Humana-United transition services agreement and concluded that the agreement provides Humana with contractual rights such that a monitoring trustee is not currently necessary to ensure United's compliance with the terms of that agreement. Third, should United fail to comply with the terms of the transition support agreement, the United States remains free to appoint a monitoring trustee, subject to the Court's approval.

IV. Conclusion

The issues raised in the four public comments were among the many considered during the United States' extensive and thorough investigation. The United States has determined that the proposed Final Judgment as drafted provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint, and is therefore in the public interest. The United States will move this Court to enter the proposed Final Judgment after the comments and this response are published in the **Federal Register**.

Dated: July 7, 2008.

Respectfully Submitted,

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In the matter of: In the United States District Court for the District of Columbia; United States of America, Plaintiff, v. Unitedhealth Group Incorporated and Sierra Health Services, Inc., Defendants.

Judge: Ellen S. Huvelle.

Filed: 2/25/2008

[Civil No. I:08–cv–00322]

Tunney Act Comments of SEIU Local 1107 on the Proposed Remedy in United Health Group Inc.'s Acquisition of Sierra Health Services Inc.

The Service Employees International Union (''SEIU'') Local 1107 provides these comments on the proposed final judgment in United Health Group Inc.'s (''United Health'') acquisition of Sierra Health Services Inc. (''Sierra''). As described herein the SEIU believes the proposed remedy in this matter is inadequate and unlikely to prevent the substantial anticompetitive effects raised by the merger. As we explain below, the proposed merger is likely to reduce competition substantially in numerous markets, including the delivery of healthcare at hospitals. By creating a dominant health insurer in Clark County. Nevada, the merger will enable UnitedHealthcare to substantially lower reimbursements to hospitals. which, as demonstrated below, will ultimately harm patient care. We believe this provided a substantial basis for the Antitrust Division, Department of Justice (''DOJ'') to challenge the merger under Section 7 of the Clayton Act, and contend that DOJ's decision to enter into the consent decree was in error. We respectfully request that the proposed consent decree is rejected and the Department of Justice sue to enjoin the merger.

The SEIU is an organization of more than 1.9 million members united by the belief in the dignity and worth of workers and the services they provide. SEIU is the nation's largest union of health care workers representing over 900,000 caregivers and hospital employees, including 110,000 nurses and 40,000 doctors in public, private, and non-profit medical institutions. SEIU is dedicated to improving the lives of all workers and their families. In Nevada, SEIU Local 1107 represents more than 17,000 registered nurses, health care workers and public employees dedicated to improving the lives of workers, their families and their communities. Our members have chosen to dedicate their lives to serving the public, and provide the first line of health care service to thousands of patients in hospitals in Nevada. In that role we experience first hand how health insurance consolidation can harm consumers by restricting the ability of all health care providers to provide high quality health care. Ultimately, when health insurers acquire and exploit their power patients and health care workers suffer.

The SEIU submits these comments on the Proposed Final Judgment (''PFJ'') pursuant to the Antitrust Procedures and Penalties Act. 15 U.S.C. 16(b–e) (known as the ''Tunney Act''). The Tunney Act requires that ''[b]efore entering any consent judgment proposed by the United States * * *, the court shall determine that the entry of such judgment is in the public interest., 16 U.S.C. 15(e)(1). In applying this ''public interest'' standard the burden is on the government to ''provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *United States* v. *SBC,* 489 F.Supp.2d 1, 16 (D.D.C. 2007), citing *United States* v. *Microsoft Corp.,* 56 F.3rd 1448, 1460–61 D.C.Cir, 1995).

The Court plays a vital role in determining the proposed decree fulfills the public interest. As Judge Greene observed in approving the AT&T settlement:

> [i]t does not follow * * * that courts must unquestionably accept a proffered decree as long as it somehow, and however inadequately, deals with the antitrust and other public policy problems implicated in the lawsuit. To do so would be to revert to the ''rubber stamp'' role which was at the crux of the congressional concerns when the Tunney Act became law.

U.S. v *American Telephone and Telegraph,* 552 F.Supp. 131, 151 (D.D.C. 1982), aff'd *sub nom., Maryland* v. *U.S.*, 460 U.S. 1001 (1983).

As detailed below, SE1U believes that the PFJ fails to meet the public interest standard. This merger will lead to an unprecedented level of consolidation and will create a dominant health insurer in Clark County. which is the largest county in Nevada and where Las Vegas is located. Allowing one health insurance company this kind of market control will harm the quality of care patients will receive in hospitals and further weaken the fragile health care system in Clark County. In particular, the merger will

- jeopardize patient safety and quality of care by reducing payments to hospitals;
- jeopardize the health care safety net;
- have a particularly adverse effect on rural hospitals;
- and, increase the number of uninsured and harm the delivery of care to the elderly.

I. The Merger Will Result in Dangerously High Nurse to Patient Staffing Ratios, Placing Patient Safety and Quality of Care in Jeopardy

The impact of the acquisition of Sierra by UnitedHealth on the quality of care in hospitals will be severe. This merger will lead to an unprecedented level of concentration, In the Clark County HMO

market UnitedHealth's market share will increase from 14% to 94%. If PPOs are included, UnitedHealth's market share increases from 9% to 60%. Even with the divestiture of the United Medicare Advarnage business as included in the PFJ. UnitedHealth's market share is over 50%. With such a dominant position UnitedHealth will be able to reduce reimbursement rates to hospitals unilaterally. Simply, hospitals will be unable to reject a ''take it or leave it'' offer from UnitedHealth.

When hospitals are forced to reduce reimbursement rates, the delivery of health care suffers. Reduced reimbursement leads to cut backs in services, less investment in equipment, and lower staffing levels. While these Comments will focus on the impact on nurses and, in turn, the impacts on patient care, these concerns are illustrative of the type of competitive problems that will arise overall from the reduction of compensation of reimbursement to hospitals.

Reductions in reimbursement force hospitals to reduce their expenses. Staff is the largest expense for hospitals, and Registered Nurses (''RNs'') represent hospitals' single largest labor expense. In Southern Nevada in particular, salaries and benefits represent 48.0% of total operating expenses,[1] and RNs comprise 76.9% of the hospital workforce.[2] Therefore, if hospitals are forced to accept low reimbursement rates, they will look to recoup their losses by cutting costs in the most logical place—their RN staff.[3] The result can be dangerously high patient-to-nurse staffing ratios.

The detrimental impact of a high patient-to-nurse ratio on patient safety and quality of care has been amply demonstrated in several markets by a recent set of academic studies, A comprehensive study conducted in 2002 and published in the Journal of the American Medical Association found that the risk of death increases by 7% for every patient in a nurse's care above a 4:1 patient to nurse ration, and increases by 16% when that ratio increases to 6:1; the study also concluded, most significantly, that there is 31% greater risk of dying in hospitals that force a single nurse to care for eight or more patients.[4] Moreover, according to a report by the Joint Commission, *Health Care at the Crossroads: Strategies for Addressing the Evolving Nurse Crisis,* understaffing is a contributing factor in 24% of sentinel events (unexpected occurrences that result in death or serious injury).[5] Indeed, patients in hospitals with fewer intensive care unit (''ICU'') nurses are more likely to suffer from complications after surgery and to have a longer length of stay in the hospital than patients in hospitals with a greater number of ICU nurses. It is also worth noting that patients are not the only ones who suffer harm to their health as a result of short-staffing: nurses are two to three times more likely to have a needle-stick injury in hospitals with low nurse staffing levels.[6]

Studies have also demonstrated that there can be better health care outcomes with adequate staffing levels. A recent study estimated that 6,700 in-hospital patient deaths could he avoided by increasing nurse staffing levels. The study further concluded that simply increasing nurse staffing levels would result in approximately 70,000 fewer adverse outcomes, including decreases in urinary tract infections, pneumonia and shock or cardiac arrest.[7]

Nurses in Nevada are already forced to work with dangerously high nurse-to-patient ratios. In 2000. Nevada ranked last among the states in RNs per capita and in per capita health services employment.[8] In 2005 Nevada ranked 49th among the states in per capita registered nurses, with only 579 RNs for every 100,000 residents, which is far below the national average of 799 RNs per 100,000 residents.[9] The RN-to-population ratios are higher in the northern part of the state and lower in Clark County. Although the number of registered nurses in Nevada has grown steadily, it has not kept pace with the state's population growth.[10] The average number of newly-minted RNs over the last five years has only been 1,264.[11] However, over the last three years, Nevada's population increased by 11.4%.[12]

Academic studies have shown that, much like the rest of the country, the epidemic of nurse understaffing in Nevada is due *not* to a shortage of registered nurses, but rather a shortage of registered nurses willing to work under the current conditions in Nevada hospitals. In 2000, active licenses were held by 12,900 registered nurses in Nevada but only 10,400 were employed in nursing.[13] In 2004 and 2005, Valley Hospital in Las Vegas reported that 206 registered nurses left employment at the hospital (Valley Hospital has approximately only 540 RNs employed at any given time).[14] At Desert Springs Hospital in Las Vegas, 137 registered nurses left employment in 2004 and 2005 (Desert Springs employs approximately only 290 RNs at any given time).[15] A case study of RNs in Nevada found that the number one reason that RN graduates leave their first job is due to patient care concerns such as unsafe patient ratios, not having

[1] Hospital Quarterly Reports. Calendar Year 2006 Summary Financial Report. Table A07 ''Operating Expenses'' and Table A08 ''Other Operating Expenses.'' Utilization and Financial Reports. Center for Health Information Analysis. University of Nevada Las Vegas. *http://www.unlv.edu/Research_Centers/chia/NHQR/Financial/NHQR_Financial_OutputCY2006%200822.xls* (Retrieved on October 15. 2007).

[2] Hospital Quarterly Reports. Calendar Year 2006 Summary Utilization Reports. Table F02 ''FTE Hospital Hours'' Utilization and Financial Reports. Center for Health Information Analysis. University of Nevada Las Vegas. *http://www.unlv.edu/Research_Centers/chia/NHQR/Utilization/NHQR_Utilization_Output_CY2006%200702.xls* (Retrieved on October 15. 2007).

[3] Kosel, Keith and Tom Olivo. ''The Business Case for Work Force Stability.'' *VHA Research Series,* 2002.

[4] Aiken. Linda H.; Clarke, Sean P.; Sloane, Douglas M.; Sochalski, Julie; Silber, Jeffrey H. ''Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction.'' *Journal of the American Medical Association,* 10/23/2002, Vol. 288 Issue 16.

[5] Joint Commission on Accreditation of Health Care Organizations. ''Health Care at the Crossroads: Strategies for Addressing the Evolving Nurse Crisis.'' 2003. *http://www.jointcommission.org/NR/rdonlyres/5C138711-ED76-4D6F-909F-B06E0309F36D/0/health_care_at_the_crossroads.pdf* (Retrieved on 3/6/07.)

[6] *Id.*

[7] Needleman, Jack, Peter I. Buerhaus, Maureen Stewart, Katya Zelevinsky and Soeren Mattke. ''Nurse Stafling in Hospitals: Is there a Business Case for Quality?'' *Health Affairs,* Vol. 25. No. 1. January/February 2006.

[8] U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions. ''State Health Workforce Profiles Highlights: Nevada. *http://bhpr.hrsa.gov/healthworkforce/reports/statesummaries/nevada.htm* (Last viewed 12/7/07).

[9] Kaiser State Health Facts. Nevada. Providers & Service Users. ''Nevada: Total Registered Nurses as of May 2005.'' *http://www.statehealthfacts.org/profileind.jsp?ind=438&cat=8&rgn=30* (last viewed 12/7/07).

[10] Packham, John, Tabor Griswold, Jake Burkey, Chris Lake. 2005 Survey of Licensed Registered Nurses in Nevada. November 2005. *http://www.nvha.net/papers/nursesurvey.pdf* Last viewed on 12/8/07.

[11] Nevada State Board of Nursing Annual Reports for years ending June 30, 2001—June 30, 2005. Includes new licenses created by examination and by endorsement.

[12] U.S. Census Bureau. American Fact Finder. Population Finder. ''Population for all Counties in Nevada, 2000 to 2006.'' *http://factfinder.census.gov/servlet/GCTTable?_bm=y&-geo&_id=0400US32&-_box_head_nbr=GCT-T1&-ds_name-PEP_2006_EST&-_lang=en&-format=ST–2&-sse=on* (Last viewed 12/7/07).

[13] U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions. ''State Health Workforce Profiles Highlights: Nevada.'' *http://bhpr.hrsa.gov/healthworkforce/reports/statesummaries/nevada.htm* (Last viewed 12/7/07).

[14] Data provided pursuant to collective bargaining information request.

[15] Data provided pursuant to collective bargaining information request.

enough time to spend with patients, and working conditions that are not conducive to safe patient care.[16] Job dissatisfaction among hospital nurses is four times greater than the average for all U.S. workers. Forty percent of hospital nurses report burnout levels that exceed the norm for health care workers and 1 in 5 hospital nurses intend to leave their current jobs within a year. Job stress and dissatisfaction increase when nurses are taking care of more patients. Each additional patient over four per nurse is associated with a 23% chance of job burnout and a 15% chance increase in odds of job dissatisfaction.[17]

Nurses also bear the brunt of the predictable results of short-staffing: every time a nurse goes to work when there are too few nurses working that shift, she puts her nursing license in jeopardy. Pursuant to Nevada statute (NAG § 632.895), a registered nurse can be subject to disciplinary action from the Nevada State Nursing Board if a patient suffers harm as a consequence of an act or an omission that could have been reasonably foreseen, up to and including suspending or revoking a nurse's license.[18] We have already explained the link between low nurse staffing levels and adverse patient outcomes including an increased risk of mortality. Yet another comprehensive study has found that rates of ''failure to rescue'' deaths increased when registered nurses were responsible for too many patients. (''Failure to rescue,'' is the death of a patient from complications including pneumonia, shock or cardiac arrest, upper gastrointestinal bleeding, sepsis or deep venous thrombosis.) Given that early identification of medical problems can decrease the risk of death in ''failure to rescue'' mortalities, inadequate staffing levels further increases the risk of harm to patients, thereby increasing the risk of a registered nurse being held responsible and losing his or her professional license.[19] In the context of this crisis, further staffing cuts as a result of this merger will drive even more Nevada nurses out of the profession.

These problems will be even more severe in Southern Nevada, where 71.1% [20] of the hospital market is controlled by for-profit companies. This concentrated for profit environment is almost unique in the U.S. A comprehensive review of clinical data from more than 4,000 hospitals in the United States found that for-profit hospitals consistently have worse outcomes than non-profit hospitals on three common medical conditions: congestive heart failure, heart attack and pneumonia.[21] The difference in quality may be attributed to the difference in accountability, while publicly-owned and non-profit hospitals are accountable to the community. for-profit hospitals are only accountable to their shareholders and, as a result, focus on strategies that increase profitability rather than strategies to benefit the community.[22]

The result of this concentration of for-profit hospital ownership is a relatively poor level of healiheare quality in Clark County. A Medicare Quality Improvement Organization, dedicated to tracking quality measures in medical settings, routinely ranks Clark County hospitals in the bottom half of our nation's hospitals in a wide-range of quality measures. In fact. some Clark County hospitals scored as low as the 6th and 7th percentile of all U.S. hospitals.[23]

The PFJ approving the United/Sierra merger will exacerbate these problems and diminish the level of health care quality. The ability of patients and doctors to determine the appropriate level of care will be weakened. Nurses that are working with inadequately low staffing levels will be faced with an additional risk to staffing levels and safe, quality patient care will be needlessly jeopardized.

II. Sierra Health Services & HCA: A Case Study of Anticompetitive Impact on Qualily & Access in Nevada

History demonstrates how the dominance of one health insurer in this market can harm the health care of children and families in our community. In Las Vegas we have already experienced the impacts of a health insurance company using its market dominance to increase their profits. In January 2007, after a contentious and public contract fight between Sierra Health Services and HCA hospitals in Clark County, Sierra Health Services terminated its contract with HCA hospitals because HCA refused to agree to the low reimbursement rates Sierra was demanding. When the contract was terminated, Sierra's 620,000 members were no longer able to access services at the three HCA hospitals in Clark County.

Children have been harmed the most by Sierra's decision. Sunrise Hospital, which is owned by HCA, specializes in pediatric care. Children are no longer able to access pediatric neurologists or pediatric radiologists in Clark County and may have to travel as far as Los Angeles to receive this level of specialized care. Children with cancer are no longer eligible to participate in protocol treatments at Sunrise Hospital. Patients who come to the Emergency Room at Sunrise Hospital who are covered by Sierra Health Services' products have to be transferred to a different hospital as soon as they are stabilized, including women in labor. Patients are sometimes forced to move from hospital to hospital to access all the care they need. We know of one patient, for example, who had to go to Sunrise Hospital to have a pacemaker removed and was then transferred to another hospital to have a new one inserted due to insurance demands.

After Sierra Health Services dropped HCA, Sierra Health Services required their enrollees to be directed to other hospitals in Clark County. Our nurses who work at the other hospitals saw first hand the impact of having 620,000 consumers suddenly redirected to their hospitals. A nurse at Valley Hospital reported that their Intensive Care Units, Emergency Room and Operating Room became overwhelmed with heart patients and other critically ill patients. Universal Health Services, the for-profit corporation that owns Valley Hospital, is already known for short staffing its Registered Nurses, so when Sierra's decision took effect, Operating Room and Recovery Room RNs and techs were on call at the hospital for 16–20 hours

[16] Bowles, Cheryl and Lori Candela. ''First Job Experiences of Recent R.N. Graduates.'' *Journal of Nursing Administration.* 2005.

[17] Aiken, Linda H., Sean P. Clarke, Douglas M. Stone, Julie Sochalski and Jeffrey H. Silber. ''Hospital Nurse Staffing and Patient Mortality, Nurse Burnout and Job Dissatisfaction.'' *Journal of the American Medical Association,* Vol. 288. No. 16, 10/23/2002.

[18] Nevada Administrative Code. Chapter 632. *http://www.leg.state.nv.us/NAC/NAC-632.html.*

[19] Needleman, Jack and Peter Buerhaus, Soeren Mattke, Maureen Stewart and Katya Zelevinsky, ''Nurse Staffing Levels and the Quality of Care in Hospitals.'' *New England Journal of Medicine,* Vol. 346, No. 22. 5/30/2002.

[20] Quality Care Nevada. ''Hospitals and Health Systems.'' *http://www.qualitycarenevada.org/index.asp?Type=B_BASIC&SEC={7707D6CB–3079–4EF0-A9D6-B81FB8D31E7F}.*

[21] Landon, Bruce E.. Sharon-Lise T. Normand, Adam Lessler, A. James O'Malley, Stephen Schmaltz, Jerod M. Loeb and Barbara McNeil. ''Quality of Care for the Treatment of Acute Medical Conditions in U.S. Hospitals.'' *Arch Intern Med,* Vol. 166, Dec 11/25, 2006.

[22] Physicians for a National Healthcare Program. ''New England Journal of Medicine Article Says Evidence Against For-Profit Hospitals Now Conclusive.'' August 1999. *http://www.pnhp.org/news/1999/august/new_england_journal_.php* (Last viewed on 12/7/07).

[23] Health Insight. *http://www.healthinsight.org* (Last viewed on 10/31/07).

every day. Emergency Room RNs had to take 4 to 8 patients each, and patients were forced to stay in the Emergency Room for 2–3 days before they were able to he transferred to a bed in Intensive Care.

Sixteen months have passed since the contract between Sierra Health Services and HCA hospitals in Clark County was severed, and patients are still not able to access care at these hospitals. At Sunrise Hospital, the census and case load continue to be low and patients continue to be refused treatment. Nurses who work at HCA hospitals have seen their hours cut and face the threat of layoffs. Many registered nurses have had to find work at other facilities or have used up all of their vacation time because there is not enough work for them. Registered Nurses have had to quit working at Sunrise Hospital because there have not been enough hours for them to work and they have been unable to pay their mortgage.

SEIU Local 1107 believes that the HCA example demonstrates the likely anticompetitive effects from the UnitedHealthcare/Sierra merger. When an insurance company is in a dominant position, it can demand dramatically lower reimbursement rates from hospitals. Most hospitals have few alternatives but to accept a take-it-or-leave-it offer from dominant health insurer. But even if they reject such an offer, it is important to recognize that the harm to consumers will not be limited simply to UnitedHealthcare/Sierra consumers. For those consumers, there is one less hospital outlet available for them to access care. But for all consumers the termination of a hospital from an insurer network imposes significant costs. Ultimately, the increased costs of serving Sierra patients at other hospitals are spread to all consumers who use those alternative hospitals as the level of care diminishes.

III. The Merger Will Create a Crisis for the Clark County's Safety Net Services by Placing Additional Strain on Nevada's Only Public Hospital

The United/Sierra merger will also harm Clark County's health care safety net by creating a crisis for Nevada's sole public hospital, University Medical Center (UMC), located in Las Vegas.

University Medical Center has served Southern Nevada for 75 years. It operates Nevada's only Level 1 Trauma Center, Nevada's only burn care facility and the only HIV inpatient unit in Southern Nevada. It also serves as the primary clinical campus for University of Nevada School of Medicine, Its Primary and Quick Care network provides primary and urgent care access to more than 300,000 patients each year.[24]

UMC treats the vast majority of the uninsured in Clark County and serves as the community's safety net hospital in Las Vegas. UMC cares for 44% of all of Clark County's Medicaid patients and 48% of Clark County's self-pay patients and has provided $280 million in charity care in the last 5 years. At the same time, UMC cares for less than 11% of the market for each of the better paying Medicare and commercial insurance.

UMC's ability to provide essential services is continuously threatened by its poor payer mix and the financial instability that that brings. UMC operates near capacity, with an occupancy rate of 84.5%, but its average operating margin for the last four years has been −3.9% because of its poor payer mix. UMC's expenses have been increasing at a higher rate than revenue since 2001, and with the rate of uninsured predicted to increase by 24% by 2021 in Clark County, this deficit is expected to continue.[25] In fiscal year 2006 UMC incurred an operating deficit of approximately $34.3 million and the operating deficit is projected to reach $60 million in fiscal year 2007.[26] Given UMC's precarious circumstances, if one insurance company were permitted to obtain market dominance, any actions that increase the number of uninsured or underinsured will severely undermine the ability of UMC to meet its obligations in providing a community safety net for Nevadans. For example, if as a result of the merger, United-Sierra dramatically raises premiums and increases the numbers of uninsured and underinsured individuals (which we discuss further below), this will only increase the demand on UMC's already over-taxed services.

Yet another way UMC will be harmed if only one insurance company insures a large percentage of the patients at a single hospital is in the area of claims resolution. Any difficulties in resolving outstanding claims will have a significant impact on the ability of the public hospital to meet its public service obligations. In fact, UMC has already had precisely this kind of trouble with UnitedHealth. Modern Healthcare reported that since UnitedHealth took over PacifiCare in 2005, UMC has had trouble with UnitedHealth's claims payment process and has had difficulty getting claims resolved.[27] If this merger is approved and these problems persist, the effects will be on a much bigger scale and it will put essential medical services at risk. UMC cannot afford the financial and operational havoc that unpaid or unresolved claims could have on their ability to provide services.

IV. The Merger Will Exacerbate the Condition of Nevada's Most Vulnerable Populations: the Uninsured and Underinsured, and the Elderly

The acquisition of Sierra Health Services by UnitedHealth will result in UnitedHealth dominating a faction of the market and possessing the power to unilaterally set the price for health insurance premiums. If individuals and/or employers are unable to afford the premiums, they will have no other health insurance options available to them and we will see an increased number of uninsured in Las Vegas.

Approximately 18% of Nevadans live without insurance, which is higher than the national average of 16%. Seventeen percent of children in Nevada live without health insurance, higher than the national average of 12%.[28] The uninsured rate in Clark County grew 31% from 2000–2006 and is expected to grow at least another 24% in the next 15 years.[29]

When patients do not have insurance they are more likely to delay seeking treatment and they are more likely to obtain their care in the emergency room. When we see them in the hospital they are much sicker than they would have been otherwise. They are more likely to have a longer length of stay. If their insurance will not cover their care they need while they are in the hospital they are more likely to have a delayed recovery and make repeat visits to the hospital.

Living without insurance can have dire consequences. In rural Nevada, there are a high number of uninsured pregnant women. When laboring moms come to the hospital with no medical records because they were unable to afford prenatal visits, a danger is posed to the mother and the child.

This merger will increase the number of underinsured in Clark County. If UnitedHealth decides that they will no

[24] Lewin Group. Clark County Final Summary Presentation,'' February 20, 2007, Slide 54.

[25] Lewin Group. Clark County Final Summary Presentation,'' February 20, 2007, slide 5, 7 & 63.

[26] University Medical Center Public Outreach Summary Report.'' Presented to the Clark County Board of County Commissioners on 9/4/2007.

[27] Benko, Laura B. ''All Bets are Off: Bigger, Yes, But Better?'' *Modern Healthcare.* 3/19/2007.

[28] Kaiser Family Foundation. State Health Facts. ''Health Coverage & Uninsured.'' *http://www.statehelathfacts.org/profilecat.jsp?rgn=30&cat=3* (Last viewed on 10/30/07).

[29] Lewin Group. ''Clark County Final Summary Presentation.'' February 20, 2007, slide 37 & 38.

longer provide coverage for certain kinds of care than that decision will leave more than 808,000 people in Nevada.[30] approximately 32.4% of the population,[31] with a choice of either going without necessary care or paying for that care out of their own pocket. SEIU Local 1107 members represent a large number of UnitedHealth's potential consumers; approximately 74.0% of SEIU Local 1107 members currently have Health Plan of Nevada (Sierra's HMO product) as their only HMO option.

Increasing the number of uninsured and underinsured will lengthen emergency room wait times and impact the quality of the care we provide at our hospitals. Hospitals are mandated by law to provide care to anyone who asks for medical treatment and, because of this, people use the ER for everyday medical problems. We are inundated with non-emergent patients that have no other place to go to receive health care. The burden takes nurses and doctors away from treating truly emergent, life-threatening patients and creates emergency room wait times that can last 6 to 8 hours. If ones insurer provides coverage to a large percentage of people in the community and that insurer decides to raise premiums, the number of uninsured or underinsured residents will increase, and all of the problems associated with that will increase as well.

Clark County is already in a perilous position of being unable to provide the appropriate level of care to elderly and disabled residents. Clark County hospitals are short staffed and do not have enough nurses to provide necessary care, The County is also suffers from a shortage of doctors, dentists and almost every other health care professional.[32] A Veterans Administration official stated that these shortages will eventually lead to premature deaths, intense strain on families and missed diagnosis that will cause patients to suffer.[33]

* * *

We believe that the PFJ thus to address the substantial competitive concerns raised by UnitedHealth's acquisition of Sierra and should he rejected by the Court.

[30] Robison, Jennifer. ''Mergers and Acquisitions: Official OKs Sierra Health buyout.'' *Las Vegas Review Journal.* 8/28/2007.

U.S. Census Bureau. Population Finder. Nevada. Population estimates in 2006: 2,495, 529. *http://factfinder.census.gov/servlet/SAFFPopulation?_event=Search&_name=&_state=04000US32&_country=&_cityTown=&_zip=&_sse=on&_lang=en&pctxt=fph* (Last viewed on 10/30/07)

[32] Hidalgo, Jason, 6/17/2007.

[33] Hidalgo, Jason, 6/17/2007.

Respectfully submitted,

Jane McAlevey, Executive Director, *Service Employees International Union, Local 1107.*

Chris Giunchigliani, Commissioner, Board of County Commissioners, Clark County Government Center, 500 S Grand Central Pky, Box 551601 Las Vegas, NV 89155–1601, (702) 455–3500 Fax: (702) 383–6041

May 14, 2008.

Joshua H. Soven, Chief, Litigation I Section, U.S. Department of Justice, Antitrust Division, 1401 H Street, NW, Ste. 400, Washington, DC 20530

RE: Tunney Act Comments, *United States* v. *UnitedHealth Group*, Civil Case No. 08–0322

Dear Mr. Soven:

As an individual Commissioner of Clark County, I am submitting these comments to express my serious concerns with the proposed final judgment entered into by the U.S. Department of Justice (''DOJ'') with UnitedHealth Group, Inc. and Sierra Health Services, Inc. over the UnitedHealth/Sierra acquisition. I believe that this proposed final judgment is inadequate to resolve the very serious competitive concerns raised by this merger.

UnitedHealth's acquisition of Sierra will create a single health insurance company that will dominate the Clark County market. By combining these two companies, a single firm will have over a 50% share of the commercial health insurance market. This single firm will have substantial power to dictate the terms and conditions in which employers, particularly small employers, will be forced to purchase health insurance. Clark County is a significant distance from other major metropolitan markets arid the commercial health insurance market has traditionally been dominated by a small group of firms.

The DOJ's decree is inadequate because it fails to recognize the potential competitive harm from the merger on employers who purchase insurance, and uninsured and underinsured individuals in Clark County. Clark County is the largest county in Nevada with a population of 2 million individuals, over 300,000 of which are uninsured, over 17% of the Clark County population. This merger is of particular concern for the county, which because it operates the largest public hospital in Nevada, University Medical Center (''UMC''). UMC is the safety net healthcare facility for the county. Uninsured and underinsured individuals use UMC as their primary source of healthcare services.

This merger, by permitting the creation of a single dominant health insurer in Clark County will substantially increase the costs of numerous commercial health insurance products, ultimately harming the consumers in Clark County.

This, in turn, will increase the number of uninsured individuals. This impact will be particularly felt by relatively small employers in Clark County. As the cost of insurance increases substantially, small employers will be increasingly unable to provide health insurance to their employees, and in turn this will further substantially increase the number of uninsured individuals in the county. Those individuals must rely on UMC for most of their healthcare services. Thus, the merger will ultimately increase the cost of healthcare services in Clark County. Moreover, this merger will diminish the service and quality of health care that patients receive as more demand is placed on the services of UMC.

The Nevada State Attorney General filed a complaint and a final judgment simultaneous to the DOJ action. The Attorney General was able to secure some modest relief to address the concerns of UMC, including the payment of overdue claims for UMC. Although these remedies aim to solve some ongoing problems between UnitedHealth and UMC, they do not provide any long-term relief to protect the interests of UMC, the uninsured, or Clark County. Now that the merger is consummated. Clark County is left dealing with an incredibly powerful health insurance company that can unilaterally reduce reimbursement, which in turn will significantly diminish the ability of the county to deliver adequate services to both insured and uninsured individuals.

I believe that the DOJ's proposed enforcement action should be rejected, and the Department should re-open its investigation to secure adequate relief to protect the uninsured individuals in Clark County and the concerns of the County itself.

Sincerely,

Chris Giunchigliani, *Commissioner.*

Congress of the United States

U.S. House of Representatives

Committee of Small Business

2561 Rayburn House Office Building

Washington, DC 20515–0315

May 15, 2008.

VIA E-MAIL

The Honorable Thomas O. Barnett, Assistant Attorney General for Antitrust, c/o Joshua H. Soven, Chief, Litigation I Section, U.S. Department of Justice, Antitrust Division, 1401 H Street, N.W., Suite 4000, Washington, DC 20530

RE: Tunney Act Comments, *United States* v. *UnitedHealth Group Incorporated*, Civil Case No. 08–0322

Dear Assistant Attorney General Barnett:

These comments are submitted pursuant to the Tunney Act [1] regarding the Proposed Final Judgment (PFJ) filed by the U.S. Department of Justice (DOJ) with the U.S. District Court for the District of Columbia in *United States* v. *UnitedHealth Group Incorporated*, Civil Case No. 08–0322.

The Tunney Act requires the Court to determine whether the PFJ is in the public interest.[2] In making this determination, the Court must carefully consider the fact that entry of the PFJ will profoundly reduce competition in the health care markets of Clark County and the State of Nevada, and pose significant risks to consumers, physicians and small businesses. The public

[1] 15 U.S.C. §§ 16(b)–(h).

[2] 15 U.S.C. § 16(e).

benefit arising from entry of the PFJ is not readily apparent.

While the Department of Justice (DOJ) took steps to protect senior citizens by requiring the divestiture of Medicare Advantage related assets, I am concerned the PFJ does not adequately protect the rest of the public, including small businesses, healthcare providers and patients.

On October 25, 2007, the Committee on Small Business held a hearing entitled *Health Insurer Consolidation—The Impact on Small Business.* The Committee heard from witnesses representing small businesses, the medical community and consumers who expressed concern regarding the growing trend of consolidation in the health insurance industiy.

Witnesses made the following comments at the hearing:

''* * * consolidation has left physicians with little leverage against unfair contract terms that deal with patient care and little control over their own employees rising health insurance premiums.'' [3]

''The lack of competition among health insurers absolutely affects my insurance cost, as well as the quality and scope of coverage. Our state's [Illinois] non-competitive health care insurance environment, due to the monopoly of one or two carriers, places all the leverage in the hands of the insurers. I can't vote with my feet and dollars if I have no alternatives from which to select.'' [4]

''Consolidation of health insurance plans have [sic] created a profound imbalance that hurts the ability of family physicians to negotiate contracts. This is harmful to our practices. but also means that many of our patients cannot find the primary care physicians who accept their insurance.'' [5]

''Health insurance consolidation has in part created a take it or leave it market for small businesses. Reduced competition through consolidations both of insurance carriers and health insurance carrier provider networks has led to increased pricing (and) fewer choices for small businesses and their employees.'' [6]

The hearing record is included as part of this comment.

Access to health insurance is an area of key concern to small businesses. The rising cost of health care is regularly cited by small firms as one of their biggest worries. Small businesses need to have choices in the health insurance marketplace. In addition, mergers should not be permitted that enable a health insurer to reduce compensation to physicians below competitive rates. If the playing field for health care providers is not level, quality of care declines and patients ultimately suffer.

The health insurance marketplace has become increasingly consolidated in recent years. Consolidation has left small businesses with fewer choices and physicians with diminished leverage to negotiate with plans. Econometric evidence shows that in the managed care field, an increase in the number of competitors is associated with lower health plan costs and premiums; conversely, a decrease in the number of competitors is associated with higher health plan costs and premiums.[7] In the majority of metropolitan areas, a single insurer now dominates the marketplace. If individuals and small businesses cannot get coverage through the dominant insurer in these areas, they may not be able to find alternatives.

Because mergers of health insurers affect access to health care and influence the quality of medical services to consumers, they command great scrutiny.

To maintain competition in the marketplace, the proposed acquisition of Sierra Health Services, Inc. (''Sierra'') by UnitedHealth Group Incorporated (''United'') requires the divestiture of more assets than merely those related to United's Medicare Advantage business in the Las Vegas area. Sierra is United's largest rival in the state of Nevada. The level of concentration posed by this merger is tremendous. A combined United-Sierra would have a nearly 80 percent share of the commercial HMO market in Nevada and almost a 94 percent share of the commercial HMO market in Clark County.

DOJ notes that ''United and Sierra together account for approximately 94 percent of the total enrollment in Medicare Advantage plans in the Las Vegas area,'' and that the ''acquisition is likely to reduce competition substantially in the sale of Medicare Advantage plans in the Las Vegas area in violation of Section 7 of the Clayton Act.'' [8] Similar effects on competition will likely arise both in the commercial HMO market, which will see virtually the same levels of concentration as the Medicare Advantage market, and the market for the purchase of physician services. The PFJ fails to address this diminishment of competition in these markets in Las Vegas and the State of Nevada.

It is critical that the Court consider the following factors in evaluating the PFJ:

The PFJ Could Enhance United's Market Power and Hurt Small Businesses

United will go from having a 12 percent share of the HMO market in the state of Nevada to an 80 percent share. In Clark County, the market share will surge from 14 percent to 94 percent. By allowing the two largest competitors in the state to merge, small businesses will face severely diminished options in health insurance plans. The insurance marketplace in Nevada and Clark County is already highly concentrated—which necessitates an even higher level of scrutiny. With such a dominant market position, a combined United-Sierra could attain market power to raise prices to small businesses above competitive levels. Small businesses will have few alternatives to a combined United-Sierra and as a consequence, will be stuck with higher premium costs. If costs rise above competitive levels more small firms will stop providing coverage to employees, increasing the number of Nevada's uninsured.

Additionally, it is important to contemplate that existing barriers to entry in the HMO market are extremely high. It is unlikely that a combined United-Sierra will face any new competitors in Nevada in the near future.

The PFJ Could Enhance United's Monopsony Power and Hurt Physicians and Patients

With such an overwhelming market share, the combined United-Sierra could reduce compensation for providers to the point where it is below competitive levels. Lower service, poorer quality and reduced access to health care could result. Physicians and other providers may not have sufficient alternatives to allow them to circumvent the compensation decreases of a combined United-Sierra. The costs for physicians to switch to other health care insurers are substantial as physician time is valuable and it can be difficult for a physician to quickly replace lost patients. With such a dominant market share and high switching costs, physicians may find that, when faced with lower reimbursement, they are unable to switch from a combined United-Sierra to another insurer. If this is the case, a combined United-Sierra could exercise market power against health care providers.

I appreciate consideration of the above mentioned issues. I am concerned that the PFJ does not adequately preserve competition in the health insurance marketplace for small businesses, physicians and consumers.

Sincerely,

Nydia M. Velázquez,
Chairwoman.

Full Commi1tee Hearing on Health Insurer Consolidation—The Impact on Small Business

Committee on Small Business

United States House of Representatives

One Hundred Tenth Congress

First Session

October 25, 2007.

Serial Number 110–55

Printed for the use of the Committee on Small Business
Available via the World Wide Web: *http://wwwaccess.gpo.gov/congress/house*
U.S. Government Printing Office
39–376 PDF Washington : 2007
For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

House Committee on Small Business

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Heath Shuler North Carolina
Charlie Gonzalez, Texas
Rick Larsen, Washington

[3] Statement of Dr. William G. Plested, III, Immediate Past President. American Medical Assn.

[4] Statement of Robert Hughes. President of the National Association for the Self-Employed (quoting a member).

[5] Statement of Dr. James D. King, President, American Academy of Physicians.

[6] Statement of James R. Office, General Counsel, Victory Wholesale Grocers.

[7] *Examining Health Care Mergers in Pennsylvania:* Hearing Before the Senate Judiciary Committee, 110th Congress (April 9, 2007) Statement of Lawton Burns, Professor, Wharton School of Business.

[8] 73 **Federal Register** 12763 (March 10, 2008).

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Full Committee Hearing on Health Insurer Consolidation—The Impact on Small Business

Thursday, October 25, 2007.
U.S. House of Representatives,
Committee on Small Business,
Washington, DC.

The Committee met, pursuant to call, at 9:30 a.m., in Room 2360 Rayburn House Office Building, Hon. Nydia Velázquez [Chairwoman of the Committee] presiding.

Present: Representatives Velázquez, Gonzalez, Cuellar, Altmire, Clarke, Ellsworth, Sestak, Higgins, Chabot, Bartlett, and Fallin.

Opening Statement of Chairwoman Velázquez

Chairwoman Velázquez. Good morning. I call this hearing to order to address Health Insurer Consolidation—The Impact on Small Business.

Access to health insurance is an area of concern to small businesses. The rising costs of health care are regularly cited by small firms as one of their biggest worries. Small businesses need to have choices in the health insurance marketplace. It is imperative that the marketplace is diverse and competition flourishes.

It is also critical that small medical providers are able to continue offering services. Physicians and other providers must be able to operate on a level playing field with health insurers and be reimbursed at fair rates. If not, quality of care will decline, and it is the patient who ultimately will suffer.

Consolidation in the health insurance industry is one area of special concern that has a direct impact on these issues. Because these mergers affect access to care and influence the quality of medical services, they command careful scrutiny by regulators. Unfortunately, the health insurance industry, like a number of other industries, has seen a general lack of enforcement of antitrust laws.

Earlier this year, The Wall Street Journal reported that the Federal Government has nearly stepped out of the antitrust enforcement business. While some mergers benefit consumers and increase the competitiveness of U.S. companies, others pose substantial risks to competition and innovation.

The health insurance marketplace has become increasingly concentrated in recent years. Consolidation has left small businesses with fewer choices, and physicians with diminished leverage to negotiate. In the majority of metropolitan areas, a single insurer now dominates the marketplace. If individuals and small businesses cannot get health coverage through the dominant insurer, they may not be able to find alternatives.

Recent mergers in the health insurance industry have tended to not generate efficiencies that have lower costs for small businesses or improved coverage. Premiums for small businesses have continued to increase without a corresponding increase in benefits. Consumers are facing increased deductibles, co-payments, and co-insurance, which have reduced the scope of their coverage.

When operating in highly concentrated markets, physicians often find they are stuck with take it or leave it contracts. The Department of Justice has recognized that physicians face special difficulties in dealing with health insurers—namely, it is very costly for them to switch from one insurer to another.

Replacing lost business for a physician by attracting new patients from other sources is very difficult in our current health care system. Physicians face barriers in attracting potential new HMO patients, since they are filtered through an HMO plan. Physicians struggle to maintain the quality of care in the

face of reduced reimbursement—a large administrative burden.

When physicians are forced to spend less time on each appointment, ultimately it is the patients that suffer. It is essential that competition remains vibrant in the health insurance marketplace. Not surprisingly, studies have found that when competition declines premium costs generally go up. The rising costs of health care are leading to greater numbers of uninsured, and less small businesses and individuals can afford to pay premiums.

Small businesses continue to be burdened by the high cost of health care. These rising costs of health insurance is one of the primary reasons the ranks of the 46 million uninsured Americans continue to grow. Tragically, 18,000 Americans lose their lives each year because of a lack of health insurance. We need to ensure that providers are on a level playing field, and small businesses and individuals have choices when it comes to health care.

I yield now to Ranking Member Chabot for his opening statement.

Opening Statement of Mr. Chabot

Mr. Chabot. Thank you very much, Madam Chairwoman. I want to apologize for being a couple of minutes late. It was one of those mornings where just too many things were scheduled and I just couldn't make it to everything on time. So I apologize.

And I want to thank the Chairwoman for holding this important hearing on the impact of mergers and increasing concentration in the health insurance market. This hearing continues this Committee's examination of the cost of health care on small businesses, both as purchasers of health care and as providers.

The Supreme Court has stated that ''The unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality, and the greatest material progress.'' In short, competitive markets represent the cornerstone of American progress and the success of our democracy. Antitrust laws were established to protect these precious values. By providing a mechanism to ensure that competition is not unreasonably hindered, the antitrust laws can be seen as further bracing the competition foundation of this country.

When mergers occur, that may reduce competition. It behooves the Justice Department or the Federal Trade Commission to closely assess the value of these mergers. That is particularly crucial in the context of health care. When the members of this Committee travel back to their districts, they are put face to face with constituents and small business owners that struggle every day to cope with the rising costs of obtaining or providing health care.

If the number of companies that supply health insurance continues to decrease, basic economics suggest that costs of obtaining health care coverage will increase. It then becomes vital to assess the impact of industry consolidation on small business owners who already have significant difficulty in obtaining health insurance coverage.

Today, we have witnesses that represent small business purchasers of health care who will inform the Committee of the increasing difficulty that they have in obtaining health care coverage at reasonable costs that are not made any easier as concentration in the industry increases. In addition to the obvious effects on purchasers of health care coverage, it is important to remember that many providers of health care are small businesses.

If concentration increases in the health insurance industry, then the multitude of providers are faced with the market power of a very large single purchaser that will be able to dictate prices and the service rendered. And if the prices do not cover the physician's costs, physicians will stop seeing patients, thus reducing choice even more. Of course, in addition to the bulwark of antitrust laws to protect competition, another avenue is to increase competition in the provision of health insurers.

This Committee, under the former Chairman, Mr. Talent, took the lead in promoting competition in the health insurance market by creating association health plans. The House, on a number of occasions—I believe six times in a five-year period—passed association health plan legislation that unfortunately died in the Senate.

The Chairwoman, Chairwoman Velázquez, should be commended for her courageous votes in support of association health plans. Given their potential to reduce costs and increase competition, I think the Committee seriously needs to investigate the resuscitation of that concept.

I look forward to a thoughtful discussion from the panel of witnesses, a very distinguished panel I might add that we have here today, and their ideas on how to protect and improve competition in the health insurance markets. And, again, I want to thank the Chairwoman for holding this important hearing, and I yield back my time.

Chairwoman Velázquez. Thank you, Mr. Chabot.

And we are going to start with our first witnesses, and let me just take this opportunity to thank all of you for being here today. We are going to have a timer in front of you. Green means you go, and then the red one means five minutes are up. Each one of you will have five minutes to make your presentation.

Dr. Plested, Dr. William Plested, is our first witness. He served as the President of the American Medical Association from June 2006 to June 2007. Dr. Plested is a cardiovascular surgeon and has been in private practice in Santa Monica, California, for more than 35 years. The American Medical Association is the nation's largest physician group and advocates on issues vital to the nation's health.

Thank you, and welcome.

Statement of Dr. William G. Plested, III, Immediate Past President, American Medical Association, Brentwood, California

Dr. Plested. Thank you, Madam Chair. My name is Bill Plested. I am a past president of the American Medical Association and a cardiac surgeon from Santa Monica, California. I want to thank you very kindly for inviting me to testify today and for holding a hearing on this exceedingly important issue—health insurance consolidation.

Consolidation in the health insurance market is critical to the AMA, because physicians are both patient advocates and small business owners. Physicians have primary responsibility for advocating for their patients, and they also are small business that want to provide health care insurance for their employees.

Physicians' ability to perform either of these vital functions, however, has been severely compromised by growing consolidation in the for-profit health insurance market. This consolidation has left physicians with little leverage against unfair contract terms that deal with patient care and little control over their own employees' rising health insurance premiums.

As you all know, our market performs optimally when consumers have a choice of competing products and services. Increasingly, however, choice in the health insurance market has been severely restricted as health plans have pursued aggressive acquisition strategies to assume dominant positions.

In the past decade, there have been over 400 mergers. Contrary to claims of greater efficiency and lower cost, these mergers in fact have led to higher premiums and decreased patient access to care. If the current trend continues, we fear it will lead to a health care system dominated by a few companies that, unlike physicians, have an obligation to shareholders, not to patients.

Our worst fears may be realized in Nevada where we have urged the Department of Justice to block the merger of the United Health Group and Sierra Health Systems. This merger would have a devastating impact on Nevada's patients and physicians and would reverberate throughout the health care system as a harbinger of unrestricted consolidation, would drastically reduce competition, and severely limit health insurance choice for employers and individuals in Nevada.

The United-Sierra merger would give United a 94 percent HMO market—share of the HMO market in Clark County and an 80 percent share of the HMO market in the entire State of Nevada. Nevada is in need of more competition, not less. The State currently ranks 47th in the country for access to care and 45th in access to physicians. This merger would push Nevada even further down these lists by exacerbating physician shortages.

Competition is essential to the delivery of high quality health care services, and this merger would serve only to further disadvantage an already challenged Nevada health care system. Consolidation is not benefiting patients. Health insurers are recording record high profits while patient health insurance premiums continue to rise. In fact, United and Wellpoint have had seven—seven years of consecutive double-digit profit growth that has ranged to 20 to 70 percent year after year.

In addition to compelling results of the AMA's annual competition study, many areas across the country exhibit characteristics typical of uncompetitive markets and growing monopolistic behavior.

These include significant barriers to entry for new health insurers, the ability of large entrenched insurers to raise premiums without losing market share, and the power of dominant insurers to coerce physicians into accepting unreasonable and unjust contracts.

The AMA believes that the Federal Government must take steps to address the serious public policy issues raised by unfettered health insurer consolidation. The current situation in Nevada is emblematic of the total absence of boundaries and enforcement currently applied to health plan mergers.

Therefore, we respectfully encourage this Committee to urge the DOJ to enjoin the merger of United and Sierra. By so doing, the Committee would be taking a meaningful step on behalf of America's patients towards correcting the existing inequities in the health care market.

Thank you.

[The prepared statement of Dr. Plested may be found in the Appendix on page 27.]

ChairwomanVelázquez. Thank you, Dr. Plested.

Our next witness is Mr. Robert Hughes. He is the President of the National Association for the Self-Employed. Mr. Hughes has managed his own accounting practice, Hall & Hughes, in Dallas/Fort Worth, for the past 20 years. NASE represents hundreds of thousands of entrepreneurs and microbusinesses and is the largest non-profit, non-partisan association of its kind in the United States.

Welcome.

Statement of Robert Hughes, President, National Association for the Self-Employed

Mr. Hughes. Thank you very much. It is our pleasure to be here this morning, and thank you, Ms. Chairwoman, for the invitation. As a representative of over 250,000 microbusinesses across the country, the NASE is committed to addressing the issue of affordable health coverage. I am here to tell you that health care costs and coverage premiums are adversely affecting microbusiness and impairing their ability to grow, compete, and succeed.

In addition to the high cost of health coverage, it has a serious personal impact on business owners and their employees. Oftentimes, the small business will sacrifice saving for retirement, putting money aside for their children's education, and addressing other personal needs to redirect funds to health coverage in order to stay insured. Of course, the worst result of mounting premiums is dropping coverage all together, which puts their business, their employees, their family, and themselves at risk when they face even a minor medical event.

In a 2005 survey, the NASE found that the majority of microbusiness owners, those businesses with 10 or less employees, do not have for themselves, nor do they offer, health insurance to their employees. Most alarming is the rate at which premiums for microbusinesses have been increasing. In a similar health study conducted in 2002, microbusinesses indicated the median premium increase for the year before was a little over 11 percent.

In 2005, microbusiness owners were experiencing a median premium increase of over 17 percent. Premium costs are the single most important factor that determines whether a business owner will insure himself and provide coverage for employees. Thus, the key question here today is if the increasing number of mergers among health insurers is playing a role in premium increases.

The self-employed and microbusinesses purchase health insurance in either the small group market or the individual market. The small group market is much more restrictive and regulated, which reduces, in our opinion, competition and availability. The NASE believes that minimization of insurance carriers due to consolidation, compounded with a concern of high risk in the small group segment, and excessive state regulation leave small business with minimal options to set up small group health plan, and is a factor contributing to high premiums in insurance markets.

A 2005 GAO report highlighted that the median market share of the largest carrier in the small group market was 43 percent, up 10 percent from just three years earlier. The five largest carriers in the small group market, when combined, represented three-quarters or more of the market in 26 of the 34 states that participated in the GAO study. The dominance of a few carriers in the small group market was also supported by studies from the AMA and leading health insurance experts.

How, then, is this lack of competition affecting insurance premiums? Well, let me give you a quote from one of our members, a freelance writer from Geneva, Illinois. ''The lack of competition among health insurers absolutely affects my insurance cost, as well as the quality and scope of coverage I can barely afford. Our state's non-competitive health care insurance environment, due to the monopoly of one or two carriers, places all of the leverage in the hands of the insurers. I can't vote with my feet and dollars if I have no alternatives from which to select.''

David, along with other microbusiness owners, will tell you that competition plays a central role in improving quality, spurring innovation, and keeping prices down. Research has indicated that health plans have increased premiums consistently above the rate of growth in costs. Cumulative, the premium increases for the last six years have exceeded 87 percent, which is more than three times the overall increase and medical inflation of 28 percent.

Why have insurance companies increased rates at these paces? I guess the simple answer is: they can. I believe that the current state regulatory climate plays an even more critical role in keeping costs high and impairing competition. State mandates are an issue. Some believe that state mandates increase insurance premiums by as much as 20 percent or even more.

Microbusiness owners have long been a proponent of market-based solutions for dealing with our health care system. However, competition without competitors will not deliver the desired incentive for health care improvement. The NASE urges Congress to address the disparities in individual and group markets. There are over 20 million non-employer firms in America. Certainly, they have access to, and choice of, health care coverage at a very limited basis, and that issue should be addressed.

Increasing insurer competition for the strong economic market segment, addressing state insurance regulation and mandates, and creating equitable federal tax treatment for these non-employer firms, are key to increasing access to affordable health coverage.

[The prepared statement of Mr. Hughes may be found in the Appendix on page 39.]

Chairwoman Velázquez. Thank you, Mr. Hughes.

Our next witness is Dr. James D. King. He is the President of the American Academy of Family Physicians. Dr. King is in private practice in the rural community of Selmer, Tennessee. He serves as the Medical Director of Chester County Health Care Services. The American Academy of Family Physicians is one of the largest national medical organizations with more than 94,000 members in 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, and Guam.

Welcome.

Statement of Dr. James D. King, President, American Academy of Family Physicians, Selmer, Tennessee

Dr. King. Thank you. On behalf of the Academy, I appreciate the concern about the effect of consolidated health plans on family physicians. We are members of the small business community, and also are professionals concerned about the effective delivery of health care to our patients.

Consolidation of health insurance plans have created a profound imbalance that hurts the ability of family physicians to negotiate contracts. This is harmful to our practices, but also means that many of our patients cannot find the primary care physicians who accept their insurance.

According to the industry analysis, between 1992 and 2006 the number of health insurance companies dropped from 95 to 7. The American Medical Association reports that 280 U.S. markets, at least one-third of the covered lives, are members of a single largest insurer in that market. In the U.S., only two insurance companies cover one-third of all insured Americans.

This market concentration gives health plans huge power to determine the coverage and payment terms. Let me give you a snapshot of how this affects the individual member. Nearly two-thirds of the patients of a solo family physician in Colorado are insured by one commercial payer. This situation occurred because of a merger. When this doctor made the case for a payment increase to keep pace with inflation, he was told by the insurance company, ''As a solo physician, you are the weakest economic unit and must take what we decide to give.''

That single statement bluntly and accurately describes our problem. As the economic heavyweights, health plans have no incentive to agree to physician requests. When a doctor doesn't agree to the terms of the contract, the plan just removes the

practice from the network. This means that patients essentially are denied access to their physicians.

In most cases, family doctors stick to their patients and sign untenable contracts. These contracts can affect many aspects of the practice. They dictate treatment decisions, require the use of special labs, require peer-to-peer requests for prior authorizations, demand completion of multiple-page forms, and delay payment while requiring responses to endless questions.

Many insurance contracts even allow the health plan to change the terms at any time without notifying the physician simply by posting new information on their web site. These business practices may increase the profit—may increase the profits of the insurance company, but they create enormous burdens for our small and solo practices and may hurt patient care.

As a result, more primary care physicians are driven to work in other settings, such as emergency rooms, in cash only practices. Some leave medical practice all together. Worst of all, payment rates and other contract terms are unrelated to quality of care.

Let me give you another quick story. A family physician who had been honored several times as the best physician in Arizona, who had more than 100 physicians as his patients, and who received the highest possible rating from his health plans for quality and efficiency, is taking more than $100,000 out of his savings each year just to keep his practice afloat. Despite his good work, he has been unable to negotiate higher payment rates with insurers.

Speaking more broadly, insurance plans consolidate threaten—consolidation threatens the potential for quality improvement in U.S. health care. For example, family medicine and other primary care specialties are advocating for the patient-centered medical home for all Americans. This medical home would be a practice that has been transformed to offer comprehensive, continuous, and coordinated care to our patients.

Experience with health systems based on primary care in other industrialized nations have demonstrated the exceptional value of a medical home in terms of quality and cost effectiveness. However, the success of the medical home depends on a long-term relationship between the physician and the patient. This relationship can be threatened, even destroyed, if insurance companies dictate the terms of the medical practice and limit our patients' freedom of choice.

The AAFP recommends changing antitrust laws so that physicians can be true market participants. The current statutes were established years ago during a very different competitive environment. Under these outmoded laws, physicians are barred from discussing the financial aspects of their practice with any entity unrelated to their practice. In contrast, insurance companies use market share and shared economic strength to carry out near monopolistic behavior.

AAFP commends the Committee for highlighting the significant problems resulting from health insurance consolidation. Family physicians, many of whom provide health care in small and solo practices in rural and other under served areas, feel the effect of the insurance consolidation as they attempt to negotiate in an environment that is stacked against them.

Again, I want to thank you for this opportunity to provide this testimony, and I look forward to answering your questions.

[The prepared statement of Dr. King may be found in the Appendix on page 44.]

Chairwoman Velázquez. Thank you, Dr. King.

And now the Chair recognizes Dr. Chabot for the purpose of introducing our next witness.

Mr. Chabot. Thank you very much, Madam Chair. I would like to introduce Mr. Office. He is the Vice President and General Counsel for Victory Wholesale Group, which is headquartered in Springfield, Ohio. Mr. Office is currently sponsorship chair and a board member of the Southwest Ohio Chapter of Association of Corporate Counsel.

Victory is a national wholesale distributor of grocery, health and beauty, and pharmaceutical products, and we are very pleased to have a fellow buckeye here this morning. And we welcome you and are looking forward to hearing from you, Mr. Office.

Thank you.

Statement of James R. Office, General Counsel, Victory Wholesale Grocers, Springboro, Ohio

Mr. Office. Thank you, Madam Chairwoman, Representative Chabot, and members of this Committee, for inviting us to discuss this important issue.

Victory Wholesale Group appreciates the opportunity to submit these comments to the Committee. The rising and out-of-control increases in health costs is a very important subject to us and every other small business across America. Health insurance consolidations are a large contributor to the increased health costs. One of Victory's largest expenses is for the health care coverage that it provides its employees.

Let me first tell you a little something about Victory. Some of you may know something about Victory through our involvement in and grants over the many years to the Congressional Hunger Foundation. Victory is a group of family-owned separate companies. The first was established in 1979. Our businesses include a wholesale grocery distributor, a food marketing company, a public warehouse business, a contract packaging business, a pharmaceutical wholesale distributor, a promotional items distributor.

Victory has a small number of employees and businesses in over 22 states, including Ohio, New York, Florida, California, Nevada, and the Commonwealth of Puerto Rico. Health insurance is the cornerstone of benefits that Victory provides its employees. Victory has tried different health care plan models, including fully insured, self-insured, PPOs, and HMOs, with the objective to reduce our health insurance care costs, or to control their increases.

Victory, having employees around the country, has not been able to find a single affordable health care plan that covers our separate businesses and employees on a national basis with health care provider networks that can compete with the regional health care providers.

In Victory's experience, insurance consolidation has led to the decreased competition and higher prices in the market. Let me elaborate. First, we have found that controlling health care costs is nearly impossible. The health care industry is both fragmented and concentrated. It is loaded with administrative costs, it is inefficient, it is not measured. Accounting for quality and for value just simply doesn't exist.

Next, we have found that the deepest discounts and best coverage networks are offered on a regional basis. We have found that the markets where we have employees are dominated by a few large insurance carriers. Carriers with a smaller market share in these regions generally have weak hospital and doctor networks, or smaller discounts. Plans with fewer hospitals and doctors to choose from are simply not very popular with employees, and, therefore, employers.

We have found that many of the markets where we have employees have several dominant affiliate health care provider networks or groups. These are groups of one or more hospitals and physicians that have combined into an affiliation or network, and they rent these networks to insurance companies and employers.

A few dominant health care provider networks in a region can and do use their enhanced market clout to resist negotiating discounts with insurance carriers and employers. We have found that the dominant insurance carriers in the region generally price health care plans for small businesses through what I would describe as experience rating, i.e. healthy groups get fairly high prices, and unhealthy groups get very high prices.

Insurance carriers have an uncanny way of learning the health of a group, even if they don't insure your group. We have found that a single serious or major health event within a group will virtually eliminate competitive bids and result in much higher than average cost increases as well as dictated structural changes in your benefits to the group's plan at renewal.

We have found that faced with the increasing health care costs, employers and employees are faced with very few choices. I would call it a menu of the lesser of evils. These options include: 1) increasing the amount of premium that each employee pays each month; 2) increasing the co-payments or deductibles; 3) imposing changes on unhealthy lifestyles, like charging smokers or obese people more premiums; 4) incorporating higher deductibles and lower benefits into the plan design, and sometimes using like a health savings account or health reimbursement accounts, which in the end is just a cut in benefits, reducing or modifying or eliminating benefits, and providing financial incentives or disincentives to use the modified benefits.

And lastly, an option that I find is becoming a lot more common today, which is small businesses are just eliminating offering employer-provided health insurance. Historically, small businesses make up the

backbone of our nation's employers. Collectively, small businesses employ the largest number of people in the United States. Yet because each company is small, we have almost no market clout to help bring changes to our health care system.

Health insurance consolidation has in part created a take it or leave it market for small businesses. Reduced competition through consolidations both of insurance carriers and health insurance carrier provider networks has led to increased pricing, fewer choices for small businesses and their employees.

[The prepared statement of Mr. Office may be found in the Appendix on page 49.]

Chairwoman Velázquez. Mr. Office, your time is up, and they just called for a vote. So I would like to move to the next witness. And for that purpose, I recognize Mr. Bartlett.

Mr. Bartlett. Thank you very much. Mr. Scandlen wasn't in his chair when the Committee began, I suspect for the same reason I wasn't in my chair. I think we both probably came down 270 this morning. I left two hours and 15 minutes before the Committee, because I really wanted to be here on time. But, unfortunately, this was my second longest commute in 15 years of commuting that 50 miles from Frederick, Maryland, down to the Hill. So thank you very much for braving the traffic and being here this morning.

Greg Scandlen is from Hagerstown, Maryland. He is the founder of Consumers for Health Care Choices, a non-partisan, non-profit membership organization aimed at empowering consumers in the health care system. He is considered one of the nation's experts on health care financing, insurance regulation, and employee benefits.

He testifies frequently before Congress and appears on such television shows as The O'Reilly Factor, NBC Nightly News, and CNN. He has published many papers on topics such as health care costs, insurance reform, employee benefits, individual insurance programs, HSAs, HRAs, and every aspect of consumer-driven health care. Mr. Scandlen was the president of the Health Benefits Group and the founder and executive director of the Council for Affordable Health Insurance. He also spent 12 years in the Blue Cross/Blue Shield system, most recently as the director of state research at the national association.

Thank you very much for joining us today.

Statement of Greg Scandlen, President, Consumers for Health Care Choices

Mr. Scandlen. Thank you, Mr. Congressman. Thank you, Madam Chairman, and members of the Committee. I was going to ask you, Mr. Bartlett, for a note excusing my tardiness, but you have made that unnecessary. Thank you very much. I do apologize for being late, though.

I know you have a vote pending, so I will be very quick. I just want to share a couple of thoughts with you. One is that concentration of—in this market is not an accident, and it is not an inherent part of the small group market. When I was with the Blue Cross/Blue Shield Association, I was—one of my responsibilities was working with the National Association of Insurance Commissioners on their small group reform proposals back in the late 1980s.

And I can tell you, at the time the Commissioners and their staff made it very clear that these reforms would do nothing to lower cost, nothing to increase access. Their purpose was to stabilize the market, and that was their language.

And what they meant by that was they thought there was too much competition in the small group market. It was confusing for employers, and they would prefer it if there were only three or four competitors in every market. That would be easier to understand, and, frankly, probably easier for the regulators to regulate, with a smaller number of companies.

So I think the situation we have today is the direct consequence of regulatory interference with the market. Many of those regulations were well intentioned, but I think they all add to cost and complexity in this market, and many, many smaller companies decided they simply could not afford to comply with the various state and changing from year to year regulations that they had to follow. So they simply got out of the business.

Many of them were life insurance companies, and they sold off their health books to larger carriers that were—that are better able to afford the compliance costs associated with all of these regulations. And what we have today, and as the other witnesses have mentioned, we have coverage that is overpriced, inefficient, unaccountable, inconvenient, and incomprehensible to the consumer.

We need—these are, I believe, the characteristics of a non-competitive market. There is insufficient competition. If you don't like what—if you don't like what one company offers, it really doesn't matter because everybody else is offering the exact same thing at the exact same price.

This market is sorely needing innovation and efficiency. The insurance industry is notoriously inefficient. And back in the 19th century when it comes to technology and computer support, larger is not better, larger results in monopolization and a lack of innovation. And there have been some proposals that have come before the Congress that I think would help here.

One is the interstate purchase of coverage. So if I am living in Maryland, and there is a better product available in Pennsylvania, I would like to be able to purchase that product, and I don't see why I can't. Another possibility would be an alternative federal charter, so insurance companies could become like banks. They could decide whether they would like to be regulated by the states or by the Federal Government.

And if they choose the states, they are confined to doing business in the state that is regulating them. If they choose a federal charter, they can operate nationally, and Mr. Office and other multistate's smaller employers would be able to purchase the same product for all of their employees.

So I think solutions are there, but I think decisive action is needed, because this market is collapsing.

Thank you very much.

[The prepared statement of Mr. Scandlen may be found in the Appendix on page 56.1

Chairwoman Velázquez. Thank you very much.

The Committee stands in recess and will resume right after the vote.

[Recess.]

Chairwoman Velázquez. Gentlemen, the Committee is called back to order. I know the Ranking Member is on his way here.

I would like to address my first question to Dr. Plested. We all agree that it is critical that physicians are in a position to be advocates for their patients. I understand that some physicians are concerned that important decisions relating to care of patients has been taken away from them by burdensome rules imposed by insurers.

My question is, Dr. Plested, have these rules gotten more onerous as the insurance industry has consolidated? And how do these policies affect the doctor-patient relationship? Is the quality of care impacted?

Dr. Plested. Thank you, Madam Chair, and the answer to the question is unequivocally yes, quality of care is affected. The basis for patient care throughout history has been based on what we call the patient-physician relationship. And both of those partners in that relationship have the same interest, and that is the health of the patient. Regardless of how you change that, if you put anyone in between that, whether that be an insurer or an employer, if anyone else gets in between those two parties in that relationship, their interest is different.

With an insurer, the CEO of every insurance company's primary interest is his shareholders, not the patient. So that it can just—it just follows by reason that any time we dilute that basic fundamental relationship it is not in the interest of patients. And when the insurer can bludgeon the physician with paperwork, with unnecessary rules and regulations and unilateral—contracts that can be unilaterally amended, all these things that you have heard in the testimony today, that directly affects the care that those patients can get.

Chairwoman Velázquez. Have you conducted any survey among doctors regarding that doctor-patient relationship as a result of consolidation?

Dr. Plested. Specifically related to consolidation, I don't know that we have, but we have all kinds of data about what has happened to the relationship, and consolidation is an integral part of that. And it has all been detrimental.

Chairwoman Velázquez. Thank you, Dr. Plested.

Dr. King, the difficulty physicians have faced with the insurance industry is in large part based upon the size of the companies and the market share they command. Some insurance companies have grown so large that physicians have found it difficult to negotiate a contract with favorable terms. What has been the experience of your members? Are they being forced to accept take it or leave it contracts?

Dr. King. The short answer is yes. I practice in a small town in Selmer, Tennessee, west Tennessee in a rural area. And so we only have one or two major industries to begin with, and when we only have one insurance product they have as much as 30, 40, 50 percent of the patient base for us to take care of.

And I have been taking care of these patients for 20 years, and all of a sudden I

am dealing with an insurance company that has offered a contract that I know is inappropriate, that is going to interfere with the quality of care that I need to provide. And it is tough for me even to consider making a living and supply jobs for my employees. I am a small business, too. I have got—we have seven physicians, we have 39 employees that we need to supply their health care, we need to provide them with pay.

So I am a small business, but I am also providing the health care. And if I choose to eliminate 20 percent of the patients I have been taking care of I don't think too many businesses can do that. And we are seeing that every day, that they are having to either accept a contract that is not acceptable, that we know we can't make it work, or give up 30 percent of the patients we have been caring for over years.

Chairwoman Velázquez. Thank you.

Mr. Hughes, the cost of the same health benefits are likely to be higher for a small firm than for a large firm. How does this make for an unleveled playing field for your members when it comes to negotiating health insurance plans? And with increased concentration in the industry, do you expect this disparity to grow?

Mr. Hughes. The micro-employer is in a very difficult position, because they are facing regulation that places them into the small group market. So even though we may have a very small employer group of only one or two people, they are thrown into the group market that is accordingly rated based on that group experience.

What we are seeing is a significant premium rate increases as a result of that. The small group simply doesn't have a chance to compete the way the larger group does in the marketplace.

Chairwoman Velázquez. What can be done to remedy this disparity?

Mr. Hughes. Well, one of the factors involves federal taxation. It is clear that taxes affect social behavior, and it is also clear that in the Tax Code today all businesses receive an exemption for the payment of income taxes and payroll taxes on premiums that they provide for their employees for health insurance coverage.

The exception to that rule is for the sole proprietor, the self-employed individual. That particular individual does not receive a payroll tax deduction for these health insurance premiums, and accordingly must pay then 15 percent of payroll taxes on those premiums. The effect is that if the tax law were amended to be equitable to all business owners, self-employed proprietors could then reduce their premium costs by 15 percent across the board.

Chairwoman Velázquez. Thank you, Mr. Hughes.

Mr. Office, you mentioned that insurance companies may entice employers by offering low coverage rates to new groups, and then dramatically increase premiums or change benefits on renewals. You mentioned that this behavior often chases competition out of the market, thus allowing the insurer to later increase prices. What have your experiences been with such enticement rates, and what can your business do to respond to dramatically increased renewal premiums when you only have one or two other insurers to choose from?

Mr. Office. If you have any suggestions, I am open.

[Laughter.]

That is the thousand-pound gorilla that we face. You will get an insurance carrier that will come into the market. And to buy market share they will offer discounts, and most small businesses look at price. That is a critical factor. And once they have done that, you are moving—your numbers stay the same.

In any community, you have a certain number of people that are insured, and you are just moving them from this bucket to this bucket, and so this area over here loses those people and they push out of the marketplace. Once that is done, then they do increase the premiums. Or if, structurally, they say, ''Well, we will keep your premium the same, but here is the policy you are going to have next year,'' it is going to have fourth-tier pharmaceutical or it is going to have higher co-pays and deductibles, or ''we are not going to cover, you know, these procedures,'' or whatever.

But as a small business, you react to what they present to you. You don't really—and you don't have a market to go look for to say, ''Well, what About an alternative?'' So any questions are welcome.

Chairwoman Velázquez. Sure. Mr. Scandlen—and I will recognize Mr. Bartlett—I heard when you spoke about the direct consequences of state regulations that it really encourages concentration. And I know how frustrating it is. You said that one of the avenues could be interstate purchase of health insurance or federal charter.

But even without going into that, what role or how do you assess the Department of Justice role, or lack of oversight, regarding antitrust laws when it comes to consolidation?

Mr. Scandlen. I think there is an important role for antitrust enforcement here. Clearly, when there are only two or three players, when they actually merge together, that is a concern. But I, quite frankly, think that is—that is something for the—it is not a universal solution, because if there is a company that would like to sell its business to another company, because the first company simply is not profitable, then antitrust enforcement there strikes me as inappropriate.

So I guess I am reluctantly embracing antitrust in selected cases. And, for instance, in the United-Sierra merger in Nevada, my organization was quite concerned about that and communicated with the Department of Justice encouraging them to reject that merger, because here were two very strong viable companies that consumers we couldn't see would derive any benefit from—from the merger. And if consumers are not benefiting from it, then I think it—and could actually be disadvantaged by it, then I think it is a problem. But I don't see it as the number one solution to this issue.

Chairwoman Velázquez. Thank you.

Now I recognize Mr. Chabot.

Mr. Chabot. Thank you, Madam Chair.

Dr. Plested, I will start with you if I can. You noted that investigating consolidation regulators have tended to focus on physicians rather than on health insurers. Could you expand upon that a little bit? Why do you think that is so, and what should be done about that?

Dr. Plested. Well, I certainly can't testify to the motivation of the DOJ, but I can testify to what has happened, and it would appear that the doctor—an individual doctor is much less able to withstand an assault from the DOJ. And it makes their rate of caring actions that they succeed on exceedingly high, because it—an individual physician just can't withstand this.

A huge insurer certainly can, and I think the point that the Chairman just raised is exceedingly important. What can we do, or what can this Committee do? And the answer to that is it is time to draw a line in the sand and say, ''This is going to stop.'' The answers are complex, as everybody has said, and they aren't going to be solved in this testimony or this action. But to put down a marker and say this Committee from—to the DOJ, we have got to make it crystal clear that this is going to stop, and get this merger enjoined, would be the necessary first step that could be made.

Mr. Chabot. Thank you, Doctor.

Mr. Hughes, if I could turn to you next. In your written testimony, you urged Congress to address the inequitable tax treatment of health insurance for individuals purchasing coverage on their own. I really couldn't agree more with you on that, and, in fact, today I am reintroducing a bill that I have introduced in previous Congresses. Unfortunately, we haven't gotten it passed into law yet, but we are going to continue working.

It is called the Health Insurance Affordability Act, and it is legislation that would provide a tax deduction for gross income—or, excuse me, from gross income for the health insurance costs of an individual taxpayer, the taxpayer's spouse, and dependents as well. In other words, you know, large corporations obviously can fully deduct the health care costs for their employees, but an individual basically pays for their premiums and doesn't get to claim those for the most part. And a lot of small businesses also aren't able to do so, at least to 100 percent.

Could you explain how a deduction like that would help individuals in small firms?

Mr. Hughes. Well, again, going out in the individual market, as you indicate, those health insurance premiums are paid with aftertax dollars, meaning that their purchasing power has been eroded significantly. And if there is a way, a mechanism that would allow for the deduction of health insurance premiums across the board, whether employee or business or small business owner, then my sense is that it is going to have the impact of bringing more people into the marketplace, creating a marketplace that has in effect lower ultimate cost of premiums, and theoretically that should increase competition, because more insurers should go after that market niche. So we wholeheartedly support that type of legislation.

Mr. Chabot. Thank you very much.

Dr. King, in your written testimony you state that ''As a result of concentration of

insurers, many family practice physicians in small or solo practices have little leverage in negotiations with health plans.'' Could you discuss that briefly, and what effect that ultimately has?

Dr. King. I will be glad to. In fact, I can give you an example of my own practice. As I stated earlier, I practice in a small town in west Tennessee. We have a large employer there, and they changed insurances for cost, as mentioned earlier. There was no physician in my county in the network that insurance product provided. And they not only didn't come at us with a contract we wouldn't accept, they didn't offer us one at all.

Under their arrangement, all they had to do was have a doctor within 45 miles of the plant that signed up. Then, they met all the requirements they felt like they needed to do. And they wouldn't even sit down and talk to us.

And my patients had a choice to make that year. They came and saw me and we tried to work out a way that they could pay me for their services and we didn't bill their insurance, or they drove 45 miles. So they were doing back and forth for an entire year until they finally changed that plan. They chose not to make any changes at all.

So not only do they come at us and we can't negotiate, and this was every physician in the county, that, you know, they have enough, but for—with our family physicians, most of us are solo practitioners or small groups, anywhere from one doctor to maybe four or five. We have absolutely no leverage.

Mr. Chabot. Thank you very much, Doctor.

Mr. Office, you mentioned that your companies maintain multiple health insurance plans to foster competition, and to help reduce costs. How much of an impact does this make on your overall health insurance costs?

Mr. Office. I would be happy to share some numbers with you, which I came prepared to. But we range—for example, single only coverage in one geographic location where I understand there is some competition, and I am not involved in the buying there, but they are paying $177 a month per employee. And in the area that I work in, we are paying $570 a month. So there is a $400 difference. For family coverage, the difference is $450 versus $1,400. So you can see that there could be significant differences.

Now, because of the regionalization I can't go to, say, New York or Puerto Rico where I might get a lower rate and buy a plan for, you know, south—you know, southern Ohio where we have most-you know, a large group of people, or Florida. We just can't get that, because we end up with networks. We are not going to buy a plan and pay a premium and then get a network where there is no doctors in that area. Our employees will—there will be a mutiny.

[Laughter.]

Mr. Chabot. Okay. Thank you.

Mr. Office. So, you know, if you are going to pay the premium, you have to have hospitals and doctors in that network. And you don't want to make people have to change those choices. So there can be a big difference.

Mr. Chabot. One of our colleagues, John Shadegg from Arizona, has introduced a plan over the years relative to health insurance that would allow people to go across state lines and would undo some of the difficulties there are with various states having different requirements and regulations and keeping companies out that aren't necessarily in a particular state. So it is something that we probably ought to look at.

Finally, Mr. Scandlen, in your written testimony you discuss the need for innovation in the types of health insurance coverage that are offered, such as health savings accounts, for example. Howwould small businesses benefit from greater innovation? And is there anything that you would suggest this Committee or Congress do in that area to be of assistance?

Mr. Scandlen. I am not sure how you could encourage innovation other than just encouraging competition. I mean, I think it is the same thing. And there are some very, very interesting things out there. One of the things I mentioned in the testimony was the special needs plans under Medicare, and that is sort of an experiment that—that I think so far is having very good results, very interesting results.

These are insurance companies that focus on the needs of the chronically ill, and one of the reasons they are able to do that is because they receive—Medicare pays out risk-based premiums, so they are receiving premiums that enable them to service that special population.

Mr. Chabot, if I could very quickly also, in terms of the—your tax deduction for individuals, I think that is a marvelous idea, and I think it is worth remembering that up until 1983 individuals could deduct their health insurance premiums as part of the medical expense deduction, as long as, in 1983, it didn't exceed three percent of their AGI.

That was raised to 5.5 percent, and then in '87 raised to 7.5 percent. and we have seen, as that has eroded, the individual market has just gone in the tank, because that tax advantage has been withheld from people that buy individual coverage.

Mr. Chabot. Thank you very much.

I yield back, Madam Chair.

ChairwomanVelázquez. Thank you.

Mr. Gonzalez.

Mr. Gonzalez. Thank you very much, Madam Chairwoman. The issue of availability and affordability—and it transcends big business, small business, every American situated one way or another. The interesting thing, I think the government has a tremendous stake in making sure there is robust competition, because the future does hold more government involvement in assisting individuals, small business, families, in acquiring health insurance.

So availability and affordability looms large, whether it is the President's tax proposal, whether it is what Mr. Chabot was talking about, associated health plans, subsidizing premiums and such. All that is for naught if we don't have a healthy insurance industry that will provide choice, which will drive down cost, obviously. At least that is what I have used as the big picture.

Some of the things that we have covered here, though, I am wondering if it really does in any way assist in achieving that final goal of availability and affordability. I will say that I think our first witness alluded to—I guess it is the United acquisition of Sierra. Is that right? And maybe that should be a marker. Maybe we ought to pay a lot of attention to that, and put everybody on notice. And I think that point is well taken.

One thing that Dr. King pointed out—and I am thinking all short of that—is, how do we get all of the different participants fully empowered?

Chairwoman Velázquez. Will the gentleman suspend? Mr. Gonzalez. Yes.

Chairwoman Velázquez. I just would like to ask unanimous consent, and the Ranking Member agreed with me, for every member to have the opportunity to ask one question. This is going to be quite—a very disruptive session today. Right now on the floor they are going to be calling procedural votes.

So in light of that, I will give the opportunity for everyone to ask one question, since I know that some of the members of the panel have flights to catch.

Mr. González. I will be real brief, then. I will just ask Dr. King, you pointed out that maybe empowering physicians to negotiate, where presently they are prohibited by law—that was my understanding of your testimony—if you could just kind of elaborate a little bit on that, and how you see that would be beneficial to the big question of availability and affordability.

Dr. King. Well, in allowing us to be able to negotiate, or at least talk to each other, you know, about the different insurance products, about the contracts that we are being offered to make sure that we can compare, we talk doctor talk, we don't talk lawyer talk. And we need to have the ability to share information and share problems and concerns as we look at the contracts, so that we can make decisions that is the best interest for our patients.

And then, if we can negotiate that, I can see how, you know—you know, I don't know about the—you know, the consolidation of all of the insurance companies and all, but I see how the health care of my patients can improve, and we can arrive at a better plan that we take away the barriers that I try to help take care of my patients with that, so that physicians won't desert. We don't have enough primary care physicians out there. They are going into different arrangements. They are going into ERs, they are going into urgent cars, which is not where we want our patients, and they are going into markets that don't include insurance.

So we have—just to get the physicians out in the rural areas and taking care of patients like we need to, they have got to be able to negotiate and make it work.

Mr. González. Thank you. I yield back.

Chairwoman Velázquez. Thank you. Mr. Bartlett.

Mr. Bartlett. Thank you very much. You know, we don't really have much of a health care system in our country. We have a really good sick care system. It is the best in the world, and I would hope that we might move a little more toward a health care system, so maybe we wouldn't need such a big sick care system.

One of the problems in rising health care costs is the fact that health care—I am using

that word euphemistically—health care is about the only thing that most people shop for in our country and never ask the price. So they are not a careful shopper.

And one of the things that I wanted to personally do, so that I could become a careful shopper—and these were in the days before health savings accounts, which really makes a person a careful shopper, and I am a big fan of those. But absent that, when I retired 20-couple years ago, I wanted to find a catastrophic policy with a $5,000 deductible. See, I think that these little nickel and dime things just wear you out and enormously increase the cost of health care.

I can pay the first $5,000. That might be a little painful, but what I can't pay is that second half million. And I think that many of the policies drop. You have a cap at about a half million. I couldn't find a catastrophic policy with a $5,000 deductible. That ought to be a pretty cheap policy, shouldn't it? And wouldn't it make people a really careful shopper? And why don't you—why doesn't the industry offer that kind of a policy?

Mr. Scandlen. I think they are available now. And if I am not mistaken, the AMA has offered a $10,000 deductible policy to its members for a long time. So I think if you were shopping today, Mr. Bartlett, you would be able to find that.

Mr. Bartlett. Madam Chair, I would like you to encourage our people here who provide our options for health care to include that as one of the options.

Chairwoman Velázquez. Definitely.

Mr. Bartlett. Thank you very much.

Chairwoman Velázquez. Ms. Clarke.

Ms. Clarke. I want to thank our Chairwoman and our Ranking Member. This is probably one of the most critical issues facing Americans today. As small businesses, as health care providers, as consumers, we are all in a quandary and involved in the same meltdown together.

There are so many questions that I would like to ask, but I want to get an understanding of some of what is happening out there to physicians' claims. I want to ask for anyone on the panel—I have heard that health insurers have employed coercive tactics, such as re-pricing of physician claims, which results in non-contracted physicians receiving less than contracted physicians for the same service. What is re-pricing exactly, and what other manipulative practices have health insurers used to undermine a physician's bargaining power? Dr. Plested?

Dr. Plested. Re-pricing is a very interesting phenomenon. It is complex, but there have been contracts let by entities that do not provide any care. They just round up a large number of contracted doctors who will accept a price, and there are literally hundreds of these contracted groups. There are now entities called re-pricers that take every physician and match that physician by computers with every contract that they have signed for every service that they provide.

And so that when you get a bill from your insurance company that has six things on it, that may be a sign by a re-pricer to six or seven different contracts, so that he gets the lowest one. It is complex, but it is a very Machiavellian type of system.

There are also the things that the insurers can do that have been mentioned that they can unilaterally amend a contract. They can change the amount that they agreed to pay you. They can unilaterally put in screens. They have computerized screens that will reduce the amount that they pay for things that it doesn't pay the physician to charge—to try to challenge each of these. There are a multitude of monopolistic behaviors that are allowed by this.

Chairwoman Velázquez. Thank you. And I want to take this opportunity to thank all the witnesses. And I am sorry we do not have more time to spend with you, but I am very, very happy that we really had an opportunity to have this dialogue on an issue that is so important, not only for small businesses and small practitioners, but also for consumers in America.

The Small Business Committee will call on federal antitrust regulators to play a more active role in ensuring that health insurance markets remain competitive, and, to that effect, I will ask the Ranking Member to join with me in sending a letter to the Department of Justice. I will also—I already discussed with Chairman Conyers on the House floor, when we went to vote, asking him to do a joint hearing between Judiciary and Small Business to examine specific mergers that may be pending.

I know, Mr. Scandlen, that you said that this is just one aspect of a bigger picture, but we have to make sure that there is proper oversight and examination before these mergers can proceed.

With that, I thank all the witnesses for your participation. I ask unanimous consent that members have five legislative days to enter statements and supporting materials into the record, and this Committee is adjourned.

[Whereupon, at 11:45 a.m., the Committee was adjourned.]

Statement of the Honorable Nydia M. Velázquez, Chairwoman,United States House of Representatives, Committee on Small BusinessFull Committee Hearing: ''Health Insurer Consolidation—The Impact on Small Business''

October 25, 2007.

I call this hearing to order to address ''Health Insurer Consolidation—The Impact on Small Business.''

Access to health insurance is an area of concern to small businesses. The rising costs of health care are regularly cited by small firms as one of their biggest worries. Small businesses need to have choices in the health insurance marketplace. It is imperative that the marketplace is diverse and competition flourishes.

It is also critical that small medical providers are able to continue offering services. Physicians and other providers must be able to operate on a level playing field with health insurers and be reimbursed at fair rates. If not, quality of care will decline and it is the patients who ultimately will suffer.

Consolidation in the health insurance industry is one area of special concern that has a direct impact on these issues. Because these mergers affect access to care and influence the quality of medical services, they command careful scrutiny by regulators.

Unfortunately, the health insurance industry, like a number of other industries, has seen a general lack of enforcement of antitrust laws. Earlier this year, the Wall Street Journal reported that ''the federal government has nearly stepped out of the antitrust enforcement business.''

While some mergers benefit consumers and increase the competitiveness of U.S. companies, others pose substantial risks to competition and innovation.

The health insurance marketplace has become increasingly concentrated in recent years. Consolidation has left small businesses with fewer choices and physicians with diminished leverage to negotiate with plans. In the majority of metropolitan areas, a single insurer now dominates the marketplace. If individuals and small businesses cannot get coverage through the dominant insurer, they may not be able to find alternatives.

Recent mergers in the health insurance industry have tended to not generate efficiencies that have lowered costs for small businesses or improved coverage. Premiums for small businesses have continued to increase without a corresponding increase in benefits. Consumers are facing increased deductibles, co-payments and co-insurance which have reduced the scope of their coverage.

When operating in highly concentrated markets, physicians often find they are stuck with take it or leave it contracts. The Department of Justice has recognized that physicians face special difficulties in dealing with health insurers—namely, it is very costly for them to switch from one insurer to another.

Replacing lost business for a physician by attracting new patients from other sources is very difficult in our current health care system. Physicians face barriers in attracting potential new HMO patients since they are filtered through an HMO plan.

Physicians struggle to maintain the quality of care in the face of reduced reimbursements and large administrative burdens. When physicians are forced to spend less time on each appointment, ultimately, it is patients that suffer.

It is essential that competition remains vibrant in the health insurance marketplace. Not surprisingly, studies have found that when competition declines, premium costs generally go up. The rising costs of healthcare are leading to greater numbers of uninsured as fewer small businesses and individuals can afford to pay premiums.

Small businesses continue to be burdened by the high costs of health care. The rising cost of health insurance is one of the primary reasons the ranks of the 46 million uninsured Americans continue to grow. Tragically 18,000 Americans lose their lives each year because of a lack of health insurance.

We need to ensure that providers are on a level playing field, and small businesses and individuals have choices when it comes to healthcare.

I yield to Ranking Member Chabot for his opening statement.

Opening Statement

Hearing Name: Health Insurer Consolidation—The Impact on Small Business

Committee: Full Committee

Date: 10/25/2007

Opening Statement of Ranking Member Chabot

''I would like to thank the Chairwoman for holding this important hearing on the impact of mergers and increasing concentration in the health insurance market. This hearing continues this Committee's examination of the cost of health care on small businesses—both as purchasers of health care and as providers.

''The Supreme Court has stated that 'that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality, and the greatest material progress* * *' In short, competitive markets represent the cornerstones of American progress and the success of our democracy.

''The antitrust laws were established to protect these precious values. By providing a mechanism to ensure that competition is not unreasonably hindered, the antitrust laws can be seen as further bracing the competitive foundation of this country.

''When mergers occur that may reduce competition, it behooves the Justice Department or the Federal Trade Commission to closely assess the value of those mergers. That is particularly crucial in the context of health care.

''When the members of this Committee travel back to their districts, they are put face-to-face with constituents and small business owners that struggle every day to cope with the rising costs of obtaining or providing health care. If the number of companies that supply health insurance continues to decrease, basic economics suggests that costs of obtaining health care coverage will increase. It then becomes vital to assess the impact of industry consolidation on small business owners who already have significant difficulty in obtaining health care coverage. Today, we have witnesses that represent small business purchasers of health care who will inform the Committee of the increasing difficulty that they have in obtaining health care coverage at reasonable costs that are not made any easier as concentration in the industry increases.

''In addition to the obvious effects on purchasers of health care coverage, it is important to remember that many providers of health care are small businesses. If concentration increases in the health insurance industry, then the multitude of providers are faced with the market power of a very large single purchaser that will be able to dictate prices and the service rendered. And if the prices do not cover, for example, costs associated with obtaining malpractice insurance, providers will opt of accepting coverage from consumers reducing choice even more.

''Of course, in addition to the bulwark of the antitrust laws to protect competition, another avenue is to increase competition in the provision of health insurance. This Committee under the former Chairman, Mr. Talent, took the lead in promoting competition in the health insurance market by creating association health plans. The House on a number of occasions passed association health plan legislation that then died in the Senate. The Chairwoman should be commended for her courageous votes in support of association health plans. Given their potential to reduce costs and increase competition, I think the Committee seriously needs to investigate the resuscitation of that concept.

''I look forward to a thoughtful discussion from the panel of witnesses and their ideas on how to protect and improve competition in the health insurance markets.

''With that, I yield back.''

Statement of the Honorable Jason Altmire House Committee on Small Business Hearing''Health Insurer Consolidation—The Impact on Small Business''

October 25, 2007.

Thank you, Chairwoman Velazquez, for calling today's hearing to examine the impact health insurer consolidation will have on small business. Consolidation of health insurers has been on the rise in recent years. leaving fewer health care provider choices for small businesses. This committee consistently hears that cost is the number one factor when determining if a small business will offer health care coverage. As more and more health care providers merge, they are able to exert more bargaining power, leaving small businesses with limited options.

In my home state of Pennsylvania, the state's two largest health insurers, Highmark Inc. and Independence Blue Cross, announced a plan to combine the two organizations. The state is currently going through the review process and while the US. Department of Justice reviewed the terms of the consolidation and determined that it raises no antitrust or other anti-competitive issues under federal law, I am concerned that this consolidation may limit competition and drive up health insurance prices for small businesses, If the merger goes through, it is estimated that the new organization will control at least 53 percent of the state's health insurance market,

If health insurer mergers continue to follow the trend of resulting in fewer options and higher costs, more small businesses will face barriers to health care. Now and in the future as mergers are considered, it is important to ensure that choices in the health insurance marketplace remain so access to health care is not compromised.

Madam Chair, thank you again for holding this important hearing today. I yield back the balance of my time.

Statement of the American Medical Association to the Committee on Small Business, United States House of Representatives

Re: Health Insurer Consolidation—The Impact on Small Business

Presented by William G. Plested III, MD

October 25, 2007.

Division of Legislative Counsel

202–789–7426

The American Medical Association (AMA) appreciates the opportunity to present testimony to the Committee on Small Business on health insurer consolidation and its impact on small business. We commend Chairwoman Velázquez, Ranking Member Chabot, and Members of the Committee for your leadership in recognizing that the dramatic and ongoing consolidation of the health plan industry has severely diminished, if not eliminated, competition among the insurance companies to the detriment of patients and their treating physicians.

Consolidation in the health insurance market is critical to the AMA because our members are both patient advocates and small business owners. In an environment where health insurers have increasing control over patient care and decreasing accountability, physicians have primary responsibility for advocating that their patients receive the appropriate medical care covered by their health insurance. Their ability to do so, however, has been severely compromised where dominant insurers force them to adhere to contracts that create significant obstacles to providing the best possible patient care. Physicians are also vulnerable to dominant health insurer practices as small business owners. The majority of physician practices are small businesses that are attempting to provide health insurance coverage to their employees in the face of substantial health insurance premiums. The growing consolidation in the health care market and the extreme imbalance that has resulted has meant that physicians have little leverage in either of their roles as health care advocates or purchasers of insurance.

A market performs optimally when consumers have a choice of competing products and services. Increasingly, however, choice in the health care market has been severely restricted due to rampant health insurer consolidation. Large health plans have pursued aggressive acquisition strategies to assume dominant positions in various markets across the country. In fact, a few health insurers now overshadow the majority of health care markets. In the past decade alone there have been over 400 mergers.[1] These mergers have led to higher premiums and increasing problems with patient access to care. If the current trend continues, it will inevitably lead to a health care system dominated by a few publicly traded companies that operate in the interest of shareholders rather than patients.

Our worst fears may be realized in Nevada where we have urged the U.S. Department of Justice (DOJ) to block the merger of UnitedHealth Group (United) and Sierra Health Systems (Sierra). Should this merger be consummated, it will have a devastating impact on Nevada's patients and physicians and will reverberate throughout the health care system as a harbinger of future unrestricted consolidation. The AMA's Competition Study, *Competition in Health Insurance: A Comprehensive Study of U.S. Markets*, as well as the presence of several characteristics typical of uncompetitive markets, further supports the notion that competition has been and will continue to be severely undermined in Nevada and nationwide.

We believe that the federal government must take steps to correct the current

[1] Irving Levin Associates, *The Healthcare Acquisition Report,* 2001–2006 Editions.

imbalance in the market and address the deceptive, noncompetitive conduct of large, dominant health insurers. The boundaries of acceptable consolidation in the health insurance market must be reexamined and enforced so that current threats to the health care system are blocked and future harmful consolidation is deterred. Thus, we encourage the House Small Business Committee to urge the DOJ to take steps to enjoin the merger of United and Sierra in Nevada. By doing so, the Committee would be taking a meaningful step towards correcting the existing inequities in the health care market.

United-Sierra Merger

We believe that a vital component to assuring a competitive marketplace is antitrust enforcement against anticompetitive mergers and exclusionary conduct. Over the past several years, however, the DOJ has not brought any cases against anticompetitive conduct by health insurers and has challenged only two mergers since 1999, requiring onJy moderate restructuring.[2] Currently, the AMA is urging the DOJ to prevent the United-Sierra merger, which will create an exceptional level of concentration in Nevada, particularly in Clark County, resulting in higher prices, less service, and lower quality of care.

The United-Sierra merger will drastically reduce competition for the provision of health insurance to employers and individuals in Nevada. The market share for Sierra and United combined in Nevada is 48 percent, while in Clark County the combined United-Sierra market share is 60 percent.[3] For Health Maintenance Organization (HMO) based insurance, should the merger proceed, United will have an 80 percent market share of all HMOs in Nevada and a 94 percent market share of the HMO market in Clark County.[4] According to the Herfindahl-Hirschman Index (HHI), the typical measure of market concentration, the Nevada and Clark County markets would be significantly above the threshold for being considered ''highly concentrated.'' [5] Indeed, the level of concentration would be unprecedented. Where, as here, a merger produces an entity that is so disproportionately larger than any of its competitors, there is a considerably increased likelihood that the entity will be able to raise prices, decrease compensation, and reduce quality without fear of meaningful competitive market responses.

Nevada is in need of more competition, not less. It cannot afford a merger that will further restrict patient access to care. Nevada currently ranks 47th in the country for access to care, 51st in quality of care, last for immunization coverage for children under 3, 49th in access to nurses, 44th for women's mortality rates, and 45th in access to physicians—approximately 25 percent below the nationwide median, with one of the lowest physician-to-population ratios in the country.[6] The United-Sierra merger would push Nevada even further down the access to quality medical care list by exacerbating physician and staffing shortages through decreased compensation and increased use of unreasonable contracts. Competition is essential to the delivery of high quality health care services. Its absence in the face of this merger will serve only to further disadvantage the already challenged Nevada health system.[7]

Competition in the Health Insurance Market

As noted above, the competitive health care market has been steadily eroding. Health insurers have become significantly more concentrated and have used their power to the disadvantage of patients and physicians. As mentioned above, over the past 10 years there have been over 400 mergers involving health insurers and managed care organizations.[8] In 2000, the two largest health insurers, Aetna and UnitedHealth Group (United), had a total combined membership of 32 million people. Due to aggressive merger activity since 2000, including United's acquisition of California-based PacifiCare Health Systems, Inc., and John Deere Health Plan in 2005, United's membership alone has grown to 33 million. Similarly, WellPoint, Inc. (Wellpoint), the company born of the merger of Anthem, Inc. (originally Blue Cross Blue Shield of Indiana), and WellPoint Health Networks, Inc. (originally Blue Cross of California), now owns Blue Cross plans in 14 states. In 2005, WellPoint acquired the last remaining Blue Cross Blue Shield plan, the New York-based WellChoice. Consequently, WellPoint now covers approximately 34 million Americans.[9] Together, WellPoint and United control 36 percent of the U.S. commercial health insurance market.

AMA Competition Study

The effects of consolidation are particularly striking at the local and regional levels, illustrated by the AMA's Competition Study, *Competition in Health Insurance: A Comprehensive Study of U.S. Markets.*[10] Every year for the past six years, the AMA has conducted the most in-depth study of commercial health insurance markets in the country. The study analyzes the most current and credible data available on health insurer market share for 313 Metropolitan Statistical Areas (MSA5) and 44 states.[11]

In addition to its exhaustive geographic reach, the study analyzed the product market in three ways—considering only HMO products; considering only Preferred Provider Organization (PPO) products; and considering HMO and PPO products combined. For each, the study calculated the HHI,[12] which measures the competitiveness of a market overall,[13] and, applying the 1997 Federal Trade Commission/Department of Justice Horizontal Merger Guidelines (Merger Guidelines), classified them as ''not concentrated,'' ''concentrated,'' or ''highly concentrated.''[14] The results form the most extensive and accurate portrayal of the health insurance market to date. And they confirm that in the majority of health care markets competition has been severely undermined.

With regard to market concentration (HHI), the study found the following:

- In the combined HMO/PPO product market, 96 percent (299) of the MSAs are highly concentrated.
- In the HMO product market, 99 percent (309) of the MSAs are highly concentrated.
- In the PPO product market, 100 percent (313) of the MSAs are highly concentrated.

With regard to market share,[15] the study found the following for each product market:

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[2] *See United States* v. *UnitedHealth Group Inc.,* Case No. 1:05CV02436 (D.D.C. Dec. 20, 2005), available at *http://www.usdoj.gov/atr/cases/f213800/213815.htm; United States* v. *Aetna,* Revised Competitive Impact Statement, Civil Action 3–99CV1398–H (N.D.Tex, 1999), available at *http://www.usdoj.gov/atr/cases/f2600/2648.htm.*

[3] Nevada State Health Division

[4] *Id.*

[5] Merger Guidelines S. 1.51.

[6] *Nevada Strategic Health Care Plan,* Report of the Legislative Committee on Health Care, Nevada Revised Statute 439B.200, February 2007; *http://system.nevada.edu/Chancellor/University/index.htm*; *http://www.commonwealthfund.org/statescorecard/statescorecard_show.htm?doc_id=495871; http://hrc.nwlc.org/.*

[7] United claims that efficiencies produced by the merger will outweigh anticompetitive harms. As a general matter, however, efficiencies from health insurance mergers have not been passed on to patients. This is evidenced by the United PacifiCare merger, which has not resulted in lower premiums or better services for subscribers.

[8] Irving Lewvin Associates, *supra.*

[9] WellPoint Health Networks and Anthem, Inc., merged in 2004 The merged entity, WellPoint, Inc., is nearly double the size of either entity.

[10] The AMA focused on state and MSA markets because health care delivery is local, and health insurers focus their business and marketing practices on local markets.

[11] Significantly, state-level data is often misleading because in many states health insurers do not compete on a state-wide basis.

[12] The HHl is the sum of the squared market shares of each firm in the market. The more competitive the health insurance market, the lower the HHI, The less competitive the health insurance market, the higher the HHI. The largest value the HHI can take is 10,000 when there is a single insurer in the market. As the number of firms in the market increases, however, the HHI decreases. For instance, if a market has four firms, each with a 25 percent share, the HHI would be 10,000 divided by 4, which equals 2500. The HHI would continue to decrease with additional firms in the market.

[13] The HHI is not a measure specific to any one firm, although it is a function of each firm's market share, The DOJ uses the HHI when evaluating the impact of a merger or acquisition on the competitiveness of a market.

[14] Markets with an HHI of less than 1000 are classified as ''not concentrated.'' The DOJ and FTC will generally not restrict merger activities in these markets. Markets with an HHI between 1000 and 1800 are classified as ''concentrated.'' Under the Merger Guidelines, a merger in one of these markets that raises the HHI by more than 100 points may raise significant competitive concerns. Markets with an HHI above 1800 are classified as ''highly concentrated.'' A merger in a ''highly concentrated'' market that raises the HHI by more than 50 points may raise significant competitive concerns, and a merger that raises the HHI more than 100 points is presumed to be anti-competitive.

[15] The AMA measures market share of health insurers by enrollment. The combined HMO/PPO market share of an insurer is the sum of that insurer's HMO and PPO enrollment, divided by the total HMO and PPO enrollment in the market, multiplied by 100. HMO market share is that HMO's enrollment, divided by total HMO enrollment in the market, multiplied by 100. Similarly, a PPPO's market share is that PPO's enrollment, divided by total PPO enrollment in the market, multiplied by 100.

For the combined HMO/PPO product market:

- In 96 percent (299) of the MSAs, at least one health insurer has a market share of 30 percent or greater.
- In 64 percent (200) of the MSAs, at least one health insurer has a market share of 50 percent or greater.
- In 24 percent (74) of the MSAs, at least one health insurer has a market share of 70 percent or greater.
- In 5 percent (15) of the MSAs, at least one health insurer has a market share of 90 percent or greater.

For the HMO product market:

- In 98 percent (306) of the MSAs, at least one health insurer has a market share of 30 percent or greater.
- In 64 percent (201) of the MSAs, at least one health insurer has a market share of 50 percent or greater.
- In 37 percent (117) of the MSAs, at least one health insurer has market share of 70 percent or greater.
- In 16 percent (49) of the MSAs, at least one health insurer has a market share of 90 percent or greater.

For the PPO product market:

- In 97 percent (304) of the MSAs, at least one health insurer has a market share of 30 percent or greater.
- In 76 percent (238) of the MSAs, at least one health insurer has a market share of 50 percent or greater.
- In 36 percent (112) of the MSAs, at least one health insurer has a market share of 70 percent or greater.
- In 9 percent (28) of the MSAs, at least one health insurer has a market share of 90 percent or greater.

This study establishes, unequivocally, that competition has been undermined in hundreds of markets across the country. Sadly, the ultimate consumers of health care—patients—are not the ones benefiting from the consolidation. To the contrary, patient premiums have risen dramatically without any expansion of benefits, while many health insurers have posted record profits.

Market Characteristics Indicating Absence of Meaningful Competition

In addition to high market share and market concentration, many health care systems across the country exhibit characteristics typical of uncompetitive markets and growing monopoly and monopsony power. There are significant barriers to entry for new health insurers in these markets. Large, entrenched health insurers are able to raise premiums without losing market share. And dominant health insurers are able to coerce physicians into accepting unreasonable contracts.

Barriers to Entry Into the Market

Barriers to entry are relevant when determining whether a high market share threatens competition in a specific market. Where entry is easy, even a high market share may not necessarily translate into market power, as attempts to increase price will likely be countered by entry of a new competitor. On the other hand, where entry is difficult, a dominant player is able to sustain profitability amid significant price increases without fear of competition.

Most markets across the country currently display substantial barriers to entry. Start-up health insurers must meet costly state statutory and regulatory requirements, including strict and substantial capitalization requirements. To do this, they must have sufficient business to permit the spreading of risk, which is difficult, if not impossible, in markets with dominant health insurers. Indeed, it would take several years and millions of dollars for a new entrant to develop name and product recognition with purchasers to convince them to disrupt their current relationships with the dominant health insurers. The DOJ underscored the significant obstacles associated with entering certain health insurance markets in *United States* v. *Aetna,* when it noted, ''[n]ew entry for an HMO or HMO/POS plan in Houston or Dallas typically takes two to three years, and costs approximately $50,000,000.[16] Such market conditions represent insurmountable barriers for new entrants.

Premium Increases

The ability of dominant health insurers to raise premiums and remain profitable is another sign of excessive market power. This practice harms small businesses, exacerbates access to care problems, and contributes to the alarming numbers of uninsured. When premiums rise, many employers stop providing coverage, reduce the scope of benefits provided, and/or ask employees to pay a higher share of the overall premium. In some cases, small businesses must choose between growth and the provision of health insurance. Even when employers continue to offer health plans, increases in premiums, deductibles, and co-payments lead many workers to forego their employer-sponsored health insurance. In fact, according to a survey by the Agency for Healthcare Research and Quality, employee health plan participation at large companies declined from 87.7 percent to 81 percent between 1996 and 2004.[17] This declining coverage puts an enormous strain on the health care system and leads to otherwise avoidable expenditures for emergency care and other medical services.

The past several years have been marked by increasing health plan premiums and profits. In 2007, premiums for family coverage increased by 6.1 percent.[18] In 2006, premiums increased by 7.7 percent and in 2005 premiums rose by 9.2 percent [19]—in all years outpacing overall inflation by 3.5 to a full 5.7 percent.[20] Cumulatively, the premium increases during the last six years have exceeded 87 percent, with no end in sight. This is more than three times the overall increase in medical inflation (28 percent) and more than five times the increase in overall inflation (17 percent) during the same period.[21] This has directly led to an increase in the number of uninsured, which currently exceeds 47 million, or one in seven Americans. Notably, these increased premiums have not led to corresponding increases in medical benefits.

Health insurers seek to deflect attention from their huge profits by falsely asserting that physician payments are driving recent premium increases. Such claims are baseless. While premium levels have risen by double-digit amounts, physician revenues have fallen. The median real income of all U.S. physicians remained flat during the 1990s and has since decreased.[22] The average net income for primary care physicians, after adjusting for inflation, declined 10 percent from 1995 to 2003, and the net income for medical specialists slipped two percent.[23] In contrast, recent reports on health insurer profits show that the profit margins of the major national firms have experienced double-digit growth since 2001. In fact, United and WellPoint have had seven years of consecutive double-digit profit growth that has ranged from 20 to 70 percent year-over-year. Thus, it is shareholders and health insurance executives, not physicians, who are profiting within an anticompetitive market at patients' expense.

Physician Bargaining Power

Growing market domination of health insurers is undermining the patient-physician relationship and eviscerating the physician's role as patient advocate. Physicians have little-to-no bargaining power when negotiating with dominant health insurers over contracts that touch on virtually every aspect of the patient-physician relationship. This is particularly troublesome given physicians' critical role as patient advocates in an environment where health insurers have increasing control and limited accountability regarding decisions that affect patient treatment and care.

Many health insurer contracts are essentially ''contracts of adhesion.'' Contracts of adhesion are standardized contracts that are submitted to the weaker party on a take-it or leave-it basis and do not provide for negotiation. Many contracts of adhesion contain onerous or unfair terms. In the health insurer context, these terms may include provisions that define ''medically necessary care'' in a manner that allows the health plan to overrule the physician's medical judgment and require the lowest cost care, which may not be the most optimal for the patient. They also frequently require compliance with undefined ''utilization management'' or ''quality assurance'' programs that often are

[16] *United States* v. *Aetna.* Revised Competitive Impact Statement, Civil Action 3–99CV1398–H (N.D.Tex, 1999), available at *http://www.usdoj.gov/atr/cases/f2600/2648.htm.*

[17] Fuhrmans, Wall Street Journal, 8–25–06.

[18] *Employer Health Benefits, 2007 Annual Survey,* The Kaiser Family Foundation and Health Research and Education Trust.

[19] Strunk, et al, ''Tracking Health Care Costs,'' *Health Affairs* (Sept. 26, 2001), W45.

[20] Jon Gabel, et al, ''Job-Based Health Insurance in 2001: Inflation Hits Double Digits, Managed Care Retreats,'' *Health Affairs* (Sept/Oct. 2001), at 180.

[21] Kaiser/HRET: Employer Health Benefits Survey, 2005 Annual Survey.

[22] Physician Income: A Decade of Change, Carol K. Kane, PhD, Horst Loeblich, *Physician Socioeconomic Statistics* (2003 Edition), American Medical Association.

[23] Losing Ground: Physician Income, 1995–2005, Ha T. Tu, Paul B. Ginsburg, *Center for Studying Health Systems Change Tracking Report No. 15* (June 2006).

nothing more than thinly disguised cost-cutting programs that penalize physicians for providing care that they deem necessary.

In addition to interfering with the treatment of America's patients, many health insurer contracts make material terms, including payment, wholly illusory. They often refer to a ''fee schedule'' that can be revised unilaterally by the health insurer and is not provided with the contract. In fact, many contracts allow the health insurer to change any term of the contract unilaterally. In addition, these contracts frequently contain such unreasonable provisions as ''most favored payer'' clauses and ''all products'' clauses.

''Most favored payer'' clauses require physicians to bill the dominant health insurer at a level equal to the lowest amount the physician charges any other health insurer in the region. This permits the dominant health insurer to guarantee that it will have the lowest input costs in the market, while creating yet another barrier to entry. ''All products clauses'' require physicians to participate in all products offered by a health insurer as a condition of participation in any one product. This often includes the health insurer reserving the right to introduce new plans and designate a physician's participation in those plans. Given the rapid development of new products and plans, the inability of physicians to select which products and plans they want to participate in makes it difficult for physicians to manage their practices effectively.

Despite the improper restrictions and potential dangers these terms pose, physicians typically have no choice but to accept them. Any alleged ''choice'' is illusive given that choosing to leave the network often means terminating patient relationships and drastically reducing or losing one's practice. Physicians simply cannot walk away from contracts that constitute a high percentage of their patient base because they cannot readily replace that lost business. [24] In addition, physicians are limited in their ability to encourage patients to switch plans, as patients can only switch employer-sponsored plans once a year during open enrollment, and even then they have limited options and could incur considerable out-of-pocket costs.[25]

Health insurers have even employed tactics to coerce non-contracted physicians who have managed to preserve some level of bargaining power, into signing contracts. For example, a number of large health insurers are refusing to honor valid assignments of benefits executed by a patient who receives care from a non-contracted physician. This means that health insurers, rather than pay the non-contracted physician directly, pay the patient for the services provided. Similarly, many health insurers engage in the practice of ''repricing'' of physician claims (including proprietary claims edits and the use of rental network PPOs [26]), which results in non-contracted physicians receiving less than contracted physicians for the same service.[27] These and other manipulative practices are clearly designed to undermine any residual bargaining power a physician practice might have, and further depress physician payments.

Monopsony Power

In a substantial number of markets across the country, dominant health insurers have the potential to exercise monopsony power over physicians to the detriment of consumers. Monopsony power is the ability of a small number of buyers to lower the price paid for a good or service below the price that would prevail in a competitive market. When buyers exercise monopsony power in the labor market, they exploit workers in the sense of decreasing fees below their true market value. Monopsony power also has an adverse impact on the economic well being of consumers as it results in a reduced quantity of the firms' products available for purchase.

In the health insurance industry, health insurers are both sellers (of insurance to consumers) and buyers (of, for example, hospital and physician services). As buyers of physician services, health insurers are acting as monopsonists—lowering the prices they pay to a point at which physicians are forced to forego investments in new technology, reduce staff and services, and even leave the market, all of which inevitably lead to increased waiting times and reduced access to care. Moreover, because health plans have posted considerable profits without decreasing premiums, the benefits of their ability, as a buyer of services, to lower the prices they pay suppliers (physicians), have not been passed on to consumers.

In fact, the DOJ has recognized that a health plan's power over physicians to depress reimbursement rates can be harmful to patients—the ultimate consumers of health care. Such was the basis for the DOJ's decision in 2005, requiring United to direst some of its business in Boulder, CO as a condition of approving its merger with PacifiCarc.[28] Specifically, the DOJ noted that because physicians cannot replace ''lost business'' quickly, the point at which physicians are locked-into a managed care contract is significantly lower than for other businesses.[29] In the United-PacifiCare merger, the DOJ found that where the merged company would control 30 percent of physician revenues, the plan could exercise monopsony power over physicians in a manner that would lead to a ''reduction in the quantity or quality of physician services provided to patients.'' [30]

Health insurers with monopsony power can use the economic benefits of reduced reimbursement in medical care to protect and extend their monopoly position and increase barriers to entry into the market. Thus, rather than producing ''efficiencies,'' increasing monopsony power in health care markets across the country causes a number of distortions in the market that harms patients by reducing access to care.

Antitrust Law and Policy Restrictions on Physicians

Ironically, rather than focus on the health insurance industry, which, as noted above, has boasted record profits and increased premiums corresponding to recent waves of consolidation, regulators have focused on physicians, the least consolidated segment of the health insurance industry. This is confounding given the current health insurer environment. Since April 2002, the FTC has brought at least 25 cases against physician groups based upon contracting arrangements with health insurers.[31] All but one of the groups chose to settle with the FTC rather than engage in a protracted, financially devastating legal battle.[32] These actions have had a chilling effect on physician practices,

Due to the significant burdens and responsibilities associated with ''financial integration,'' the only other option currently available to physicians is so-called ''clinical integration,'' as described by the DOJ/FTC in their 1996 *Statements of Antitrust Enforcement Policy in the health Care Area.* The agencies, however, have provided little guidance on what exactly constitutes clinical integration, other than to make clear that meeting the standard requires several years of development and millions of dollars of infrastructure investment; an option that is simply not feasible for the vast majority of physicians who are not part of a large group

[24] The DOJ, in its 1999 challenge of the Aetna/Prudential merger recognized that there are substantial barriers to physicians expeditiously replacing lost revenue by changing health plans. It also noted that this imposes a permanent loss of revenue. *United States* v. *Aetna*, Revised Competitive Impact Statement, Civil Action 3–99CV1398–H (N.D. Tex, 1999), available at: *http://www.usdog.gov/atr/cases/f2600/2648.htm.* The DOJ reiterated this position in its challenge to the UnitedHealth Group/PacifiCare merger. See *United States* v. *UnitedHealth Group Inc.*, Case No. 1:05CV02436 (D.D.C. Dec. 20, 2005), available at *http://www.usdoj.gov/atr/cases/f213800/213815.htm.*

[25] *See id.*

[26] A ''rental network PPO'' exists to market a physician's contractually discounted rate primarily to third-party payers, such as insurance brokers, third-party administrators, local or regional PPOs, or self-insured employers. Rental network PPOs may also rent their networks and associated discounts to entities such as ''network brokers'' or ''repricers'' whose sole purpose is finding and applying the lowest discounted rates, often without physician authorization.

[27] ''Repricing'' practices and rental networks also deprive contracting physicians of the benefits of their contracts when they result in payment below the contracted fee schedule, These tactics make it difficult for physicians to administer their practices and undercuts efforts to make the health care system more transparent.

[28] *See United States* v *UnitedHealth Group Inc.,* Case No. I :05CV02436 (D.D.C. Dec. 20, 2005), *available at http://www.usdoi.gov/atr/cases/f213800/213815.htm.*

[29] *See id.*

[30] *Ibid.*

[31] *See* FTC website at *http://www.ftc.gov/os/actions.shtm.*

[32] At the same time, the FTC has been extremely restrictive regarding the ability of physicians to jointly negotiate with insurers, approving only three arrangements. *See http://www.brownandtotand.com/publish/en/about/news_room/ftc_ information-Par-0005-DownloadFile.tmp/4.5FTCNotice.pdf(Brown* and Toland); *http://www.ftc.gov/bc/adops/070618medsouth.pdf* (MedSouth); *http://www.ftc.gov/os/closings/staff/070921finalgripamcd.pdf* (Greater Rochester Independent Practice Association).

practice, hi fact, the few endeavors that have been approved have been limited to large practices consisting of hundreds of physicians.

Given the increasing power and size of health insurers and the corresponding decrease in physician bargaining power, the policy landscape that has resulted in aggressive antitrust enforcement actions against physicians should be reexamined. Physician joint contracting can make it possible to obtain ready access to a panel of physicians offering broad geographic and specialty coverage. In addition, non-exclusive physician networks pose no threat to competition. Physicians can independently consider contracts presented from outside the network. Likewise, health insurers that cannot reach a ''package deal'' with a physician network can contract directly with its physicians or approach a competing network. Rather than restraining trade, the physicians will have created an additional option for purchasers—a pro-competitive result. Thus, the AMA believes that less restrictive approaches to physician joint contracting will have pro-competitive benefits such as greater flexibility, more innovation, and ultimately a better health care system.

Conclusion

It is time for the federal government to address the serious public policy issues raised by the unfettered consolidation of health insurance markets. The current situation in Nevada is emblematic of the total absence of boundaries and enforcement applied to health plan mergers. The AMA's Competition Study and the presence of market characteristics that typify dominant market power, further prove that competition has already been undermined in markets across the country. This has real, lasting negative consequences for the delivery of health care in this country. Thus, we strongly urge the House Small Business Committee to lay the groundwork for reversing this dangerous trend toward a marketplace controlled by a few health insurance behemoths by encouraging the DOJ to enjoin the United-Sierra merger.

Testimony of Robert Hughes, President, The National Association for the Self-EmployedHouse Committee on Small Business ''Health Insurer Consolidation—The Impact on Small Business''

October 25, 2007.

As the representative of over 250,000 micro-businesses across the country, the National Association for the Self-Employed (NASE) is committed to addressing the issue of affordable health coverage, which is the number one concern of our members and all small businesses in our nation. I am hear to tell you that rising health care costs are significantly hurting micro-business and impairing their ability to grow. compete and succeed. in addition, the high Cost of health coverage has serious personal consequences on business owners and employees. Often times our members will sacrifice saving for retirement, putting money aside for their children's education, and addressing other personal needs to redirect funds to health care Costs in order to stay insured. Of course, the worst result of mounting premiums is dropping coverage all together which puts their business, their family and themselves at risk should they face a medical crisis.

The number of Americans living without health coverage rose in 2006 to 47 million, an increase of almost 16 percent over the previous year. in a 2005 survey, the National Association for the Self-Employed (NASE) found that a majority of micro-business owners, those businesses with ten or less employees, do not have for themselves nor offer a health insurance plan to their employees. The smallest companies are most impacted, with only 14% of companies that grossed less than $50,000 annually having health insurance compared to 70% among those grossing more than $500,000 yearly. Most alarming is the rate at which premiums for micro-businesses have been increasing. In a similar health survey conducted by the NASE in 2002, micro-businesses indicated the median premium increase from the year before was a little over 11%. However, in 2005 micro-business owners were experiencing a median premium increase of over 17%, a substantial escalation.

Premium costs are the single most important factor that determines whether a business owner will insure himself and provide coverage for his/her employees. Most importantly, if a micro-business owner cannot afford insurance for himself and family, he/she will not likely provide health benefits to employees. The issue of choice or lack there of in earner options plays a role in terms of it's affect on price. Thus, the key question here today is if increasing consolidation amongst health insurers are playing a role in premium increases.

First, I would like to highlight that the self-employed and micro-businesses purchase health insurance in two markets: the small group market and the individual market. The definition of a small group is determined by each state, though most define it as one with 50 or fewer employees. Firms in this size range looking to offer access to health insurance for their employees will look to the small group market for insurance options. However, of those currently insured, the majority of self-employed and micro-businesses have purchased individual health coverage. While micro-businesses surveyed by the NASE indicate that they believe it is an employer's responsibility to assist their employees with health coverage, the high cost to both the business and the employee in terms of cost sharing are the most significant barriers impeding business owners from providing employees with coverage. Micro-businesses may assist their employees with their health care costs by setting up a Health Reimbursement Arrangement (HRA), contributing to an HSA or increasing their take home salary to help employees pay for individual insurance but a large percentage are not setting up an employer-based small group health plan.

The health insurance options and number of carriers differ in the individual and small group market. Most states have a suitable number of insurance carriers with an array of coverage options within the individual market. The small group market is much more restrictive in terms of competition and availability. The NASE believes that minimization of insurance carriers due to consolidation compounded with the concern of high risk in this small group segment and excessive state regulation leaves small businesses with minimal options to setup a small group health plan and is a factor contributing to high premiums in insurance markets.

A 2005 GAO report highlighted that the median market share of the largest carrier in the small group market was 43%, up 10% from 2002. The five largest carriers in the small group market, when combined represented three-quarters or more of the market in 26 of co the 34 states that participated in the GAO study compared to only 19 of 34 states in 2002. Blue Cross and Blue Shield is by far the giant in this sector, growing to 44% market share in all participating states. To support the GAO findings, we see similar depictions of lack of competition from a 2006 AMA study on the nation's health insurance markets which found that 95 percent of markets had a single insurer with a market share of 30 percent or greater and 56% of markets had a single insurer with a market share of 50 percent or greater.

From the data we see a notable dominance of a few carriers in the small group market. Thus, the next question that begs an answer is how this lack of competition is affecting premiums. Any micro-business owner will tell you that competition plays a central role in improving quality, spurring innovation and keeping prices down, Thus, the NASE feels the lack of competition may be a vital element in high premium costs in the small group sector. James C. Robinson, PhD, a professor of health economics at the University of California, Berkeley, School of Public Health, in an article for Health Affairs revealed that between 2000 and 2003 health plans raised premiums consistently above the rate of growth in costs. For investors in private insurance companies, returns were tremendous and Robinson states, ''the non-profit Blue Cross and Blue Shield plans enjoyed financial results equal to or better than those of their for-profit counterparts.'' (Health Affairs, Volume 23, Number 6) According to previous AMA testimony, in 2005 premiums for employment-based insurance policies increased by 9.2 percent—outpacing overall inflation by a full 5.7 percent. Cumulatively, the premium increases during the last six years have exceeded 87 percent, which is more than three times the overall increase in medical inflation (28 percent) and more than five times the increase in overall inflation (17 percent) during the same period. (AMA Testimony to Senate Judiciary Committee, 2006) Hence, we see that premiums have consistently increased in the face of minimal competition.

However, the NASE feels that the state regulatory climate plays an even more critical role in keeping costs high and impairing competition. State mandates on coverage in all markets increase the cost of basic health coverage between from a little less than 20% to more than 50% depending on the state. The Council for Affordable Health Insurance

has identified that there are currently over 1,600 mandates in our health care system. While mandates can make health insurance more comprehensive, they also make it more expensive by requiring insurers to pay for certain health services that consumers previously funded out of their own pockets. It is likely that insurers will push that added mandate cost into premium rates. The cost that excessive mandates add to health coverage can mean the difference between a micro-business owner just purchasing coverage for himself or also providing it to his employees. Additionally, the regulatory and statutory conditions in states have created barriers that make it difficult for new carriers and new products to expand into markets. Without new carriers or competing insurance products, price will remain high when one insurance carrier dominates a market.

Micro-business owners have long been a proponent of market-based solutions for dealing with our health care system. However, ''competition without competitors will not deliver the desired incentives for health care improvement.'' (Health Affairs, Volume 23, Number 6) We must increase competition in the small group market to encourage lower premium costs which will spur micro-businesses to seek to expand coverage to their employees. We must address excessive state mandates and restrictive climates hurting innovation. Additionally the NASE urges Congress to address the disparities in the individual market since the majority of self-employed business owners are purchasing individual health insurance. Currently there are over 20 million non employer firms, in which the owner must seek health coverage on the individual market. Thus, addressing the inequitable tax treatment of health insurance for those purchasing coverage on their own will also be a key step forward to increasing access to health coverage.

The self-employed and micro-business community continues to be the backbone of our nation's economy, therefore the NASE urges you to take immediate action to alleviate the massive health cost burden laid at their feet in order to ensure their survival and that of our nation's economy.

Statement of the American Academy of Family Physicians

Submitted to the Committee on Small Business Concerning the Impact of Health Insurance Consolidation on Small Business
Presented By James D. King, MD, FAAFP, President
October 25, 2007.

Thank you, Chairwoman Velazguez and Rep. Chabot. and the members of the Small Business Committee for the opportunity to participate in this hearing today. On behalf of the 93,800 members of the American Academy of Family Physicians, we applaud your deep concern for how the consolidation of health insurance plans affects family physicians as members of the small business community, as professionals and as small employers concerned about the effective delivery of health care.

As described by the American Medical Association, the merging and consolidation of health insurance plans has created a profound imbalance adversely affecting the ability of physicians to negotiate contracts with insurers to the detriment of physician practices. This, in turn, has led to the inability of many of our patients to locate a primary care physician who can accept their insurance and still maintain financial viability.

The trend toward consolidation is persistent. The industry analysts of investment bank Shattuck Hammond reported that between 1992 and 2006, the number of competitor consolidations resulted In 95 different payers shrinking to merely seven. According to the AMAs 2005 report on Competition in Health Insurance, in 280 U.S. markets, 30 percent or more of HMO and PPO lives are covered by the single largest insurer in that market. Looking at the U.S. as a whole, only two insurers cover a third of all commercially insured lives. This market concentration gives these health plans excessive power in determining the conditions of coverage, payment and practice.

Effects on Family Physicians

How does this consolidation affect family physicians? Let me give you just two examples. In the Dallas/Fort Worth area, a 3-physician group practice has a payer mix consisting of principally three payers: 30 percent United Healthcare, 28 percent Blue Cross and 18 percent Aetna. A solo physician practice in Colorado has 60 percent of the patients his practice insured by one commercial payer, a situation that occurred as a result of a merger.

As a result of similar concentrations of payers, many family physicians in small or solo practices have little leverage in their negotiations with the health plans. As the physician in Colorado noted when he attempted to make the case for a payment increase that at least would cover inflation, he was told by the representative of a large insurance company, As a solo physician, you are the weakest economic unit and must take what we decide to give.'' Another family physician noted that because small and solo practices cannot compare financial data before they sign a contract, they find out afterwards that their payment rates are substantially less than those of larger groups that can negotiate better terms.

Further, health plans have no incentive to accede to any of a physician's requests when the plan has the unilateral ability to remove the physician from the network for not agreeing to the terms of the contract and effectively denying that physician's patients access to the practice. Physicians in this situation have little choice but to sign whatever contract is offered by the health plans. Many practices find it financially impossible to sacrifice a significant part of their patient base to take a stand against untenable contract provisions.

Declining Payment Rates and Terms of Agreement

The health plans use this negotiating power created by this pattern of consolidation to dictate smaller payments and onerous terms. In California, the mergers of PacitiCare Health Systems with United Healthcare and WellPoint Health Networks/ Blue Cross of California with Anthem, Inc. have produced fee cuts of as much as 20 to 30 percent. According to a California Medical Association survey of 500 state medical practices, 20 percent of 1,500 affiliated physicians had terminated a Blue Cross contract or planned to do so. By forcing practices to accept these cuts or lose their patients, health plans are making it more difficult for patients to secure the health care they need.

It is not only payment rates that cannot be negotiated, but the terms of the agreement cannot be challenged. Health plans affect every segment of the practice of medicine and compel treatment decisions; for example, by requiring practices to use specific labs; by determining which tests may be performed in the office; by demanding the completion of multiple-page forms that reduce the amount of time a physician has available for treating patients; and by delaying payments by requiring responses to seemingly endless trails of questions.

These requirements may enhance the profits of the insurer but they create significant burdens for practices and patients. For example, a family physician in practice outside a metropolitan area in Ohio contracts with a health insurer who changed its national laboratory arrangement that originally included two companies down to a single, exclusive laboratory arrangement. This change caused the insurer's enrollees to drive to the local hospital for lab services rather than walk across the hail from the physician's office to a duly qualified reference lab. If the physician had referred the patients to the non-participating lab across the halt, he or she could have faced fines by the payer.

Increased Un-Reimbursed Administrative Responsibilities

The insurance plans that have a large segment of the patient population also pass back to the physician practice many of their administrative responsibilities. According to a family medicine office manager, each radiology notification and authorization request now takes an average of up to ten minutes to perform with a physician peer-to-peer request adding another 10 minutes. Another physician in Arizona reported that these authorizations can often take at least 40 minutes per procedure to receive approval from the insurance plan. These administrative activities are not reimbursed by the health plan and so they have no incentive to become more efficient. The physician, in turn, is required to comply with time-consuming health plan requirements that riot only are unpaid but are increasing in a period of declining overall reimbursement.

Unilateral Contract Changes

Many contracts allow the health plan to unilaterally change the contract terms at any time, without notifying the physician, simply by posting the amended terms on the insurer's web site. Some contracts specifically forbid the physician from disclosing information about the fees that the

insurer pays to the physician, making it impossible for these physicians to inform patients about their out-of-pocket responsibility for deductible amounts under their policy. Few contracts provide physicians with payment terms spelling out how the fee schedule Will be calculated The result is more primary care physicians are driven into other care settings, such as Emergency Rooms or cash-only practices, or they leave health care altogether due to these negative contract conditions, excessive administrative requirements and downward pressure on their already slim margins.

Effect on Students and Residents

These contract imbalances concern not just the physician in practice now who is struggling to keep her business open but also the student who is looking at career options and deciding whether primary care offers a stable future. The number of medical students choosing family medicine and primary care has been declining for several years. Medical student debt averages over $200,000 upon graduation and the potential earnings has a strong effect on the student's choice of specialty. Patients' access to primary care will ultimately be reduced as more medical students choose nonprimary care residencies because of the financial uncertainty and instability of the current situation.

Effect on Small Business Community

It is important to note that the result of health plan mergers and consolidation is not the achievement of economies of scale that might be expected. Such economies would produce lower consumer premiums, which would make it possible for more small businesses, including small medical practices, to afford to offer health insurance to their employees. Instead, consolidation produces larger insurance companies wielding the kind of power and influence that leaves physicians helpless and frustrated. As a result, small businesses are not offered more affordable prices for their employees' health plans but rather fewer choices of physicians who will accept the plans that are offered.

Effect on Patients

The payment rates that the health plans dictate are unrelated to the quality of care that the physician provides to their patients. A family physician in Arizona notes that he has been honored several times as the best physician in the state and has over 100 other physicians among his patients. He receives the highest rating possible from his health plans for both quality and efficiency. Nevertheless, he is taking more than $100,000 out of his savings each year to stay in practice because he is unable to negotiate higher payment rates with the insurance companies. This situation is not only unfortunate, but it is also clearly unsustainable, If he is forced to close his practice, his patients will have lost that long-standing source of high-quality treatment, care coordination and preventive services in which they have place their faith and trust and upon which they have retied and depended. This is a sad statement of how we as a nation have allowed our health care priorities to be contaminated

Effect on Quality

Finally, the most serious effect of this rapid consolidation is to undermine the great potential for efficiency and quality improvement offered by what we are calling the patient-centered medical home. As proposed by family medicine, internal medicine, pediatrics and the osteopathic primary care physicians, the medical home is the practice that has been transformed to offer comprehensive, continuous, coordinated care. Experience with health systems based on primary care that exist in other industrialized nations amply demonstrates the value of a medical home. These practices provide guidance, assistance and responsiveness to patients navigating an increasingly complex health care system. But the patient-centered medical home depends on a long-term relationship between the physician and the patient, which is threatened and possibly destroyed if an insurance company dictates the terms of practice of medicine and preempts the patient's freedom of choice.

Conclusion

The AAFP recommends changes in existing anti-trust laws that will provide physicians with tools thai allow them to be true market participants. The current anti-trust laws were established during a very different competitive environment. Under these outmoded laws, physicians are barred from discussing the financial aspects of their practice with any entity unrelated to their practice, yet it is ciear that insurance companies ''price to the mean'' which is how the natural competitive forces are supposed to work and is what creates a dynamic market. Small and solo practice primary care physicians are excluded from that very basic business condition while market share and shear economic strength foster these near monopolistic insurer behaviors.

Again, AAFP commends the committee for highlighting the issues resulting from health insurance consolidation. Family physicians, many of whom provide health care in small and solo practices in rural and other underserved areas, feel the effects of insurance consotidation by trying to negotiate in a very disadvantageous environment. The Academy would like to work with all stakeholders to ensure a path to an improved health care system that puts the patient first and supports the sustainability of a practice that delivers high quality primary care; toward a system that places an emphasis on personalized, coordinated, primary care and that enables such patient-centered practices to fairly compete. One step in this direction would be to enact common sense changes that would modernize anti-trust laws to better support small business medical practices and to enable them to negotiate contracts with insurers from a position of equality.

Thank you for the opportunity to provide this testimony and I look forward to answering your questions.

Statement of James R. Office, Vice President and General CounselVictory Wholesale Group Springboro, OH

On Health Insurance Consolidation—The Impact on Small Business

Before the Committee on Small Business, U.S. House of Representatives, United States Congress

October 25, 2007.

Victory Wholesale Group (''Victory'') appreciates the opportunity to submit these comments. The rising and out-of-control increase in health costs, which are largely due to consolidations in the health care industry, is a very important subject to us and every other small business across America. One of Victory's largest expenses is for the health care coverage it provides to all its employees, who are called associates.

About Victory Wholesale Group

Victory is a group of family owned, separate companies; the first established in 1979. Our businesses include: a wholesale distributor of dry grocery, health and beauty care and general merchandise, with 83 employees in Ohio, 24 in Florida, 6 in Nevada, 10 in California and 17 people in 13 other states; a food marketing company with 6 people in Connecticut and 24 employees in 12 other states; a public warehousing business with 104 employees in two Ohio locations; a contract packaging business with 17 Ohio employees; an interstate trucking company with 4 Florida, 27 Ohio and 9 employees in 5 other states; a pharmaceutical wholesale distributor with 100 employees in Puerto Rico; a fundraising gift distributor with 16 New York employees and a promotional item distributor with 5 Ohio employees.

Victory's Health Insurance Benefits

Health insurance is the largest and most costly benefit that each of Victory's companies provides its associates. Insurance type's range from self-insured health plans, governed under ERISA, to fully insured health plans provided by large regional health insurers. Our companies maintain multiple health care programs, to help reduce costs and foster competition among providers, because of the widely dispersed locations of our business operations and the regional nature of health insurance providers and their support networks.

Why Victory Maintains Different Health Plans and Victory's Experience

Because Victory has employees and operations across the country, we've been unable to find a single, affordable health care plan that will cover all our separate businesses and associates. Over the years Victory has tried different types of health plans including: self-insured and fully-insured, including PPO's and HMO's. Our objective is to provide a valuable and quality health benefit that allows associates as much free choice in selecting health care providers as reasonably possible while also controlling costs for everyone.

It has been Victory's experience, that if a health plan has one, or more, participants with a serious or major health condition its competitive choices and alternatives disappear, and its premiums are increased.

Also we have found that the deepest and best discounts are offered through regional providers and networks of preferred providers that have hospitals, doctors and other health care service providers, that combine into a single entity to provide health plans with agreed pricing or discounts in exchange for the health plan steering its employees to the network. Networks are either regional with large numbers of local doctors and hospitals as members, or national with more limited numbers of doctors and hospitals, or that offer smaller discounts.

We find that controlling health care costs is nearly impossible; that the health care industry is both fragmented, yet concentrated. It's loaded with administrative costs, it's inefficient, it's not measured or accountable for quality or value. In the present system the best way to control costs is to have only young, healthy employees.

Consolidation and affiliation of hospital and physician groups standardizes patient medical information and makes it available and easily accessible to all affiliated providers that may treat the patient; but on the negative side, it creates a concentrated front to impose increases on health insurers or to resist providing discounts.

We find that insurance carriers' quotes end up largely ''experience rating'' our group's claims experience. That means they take our actual costs, add the insurance company's overhead and their desired profit and that is the premium we are quoted. We can't find plans that cover all our locations with any meaningful provider's networks or discounts. Thus we are forced to shop on a local basis from a limited number of carriers for separate groups with small numbers of employees.

Further, we found that in most of the regions in which we sought quotes there were only one or two dominant insurers that essentially controlled each local market. And to make matters worse, those regions also were dominated by one or two major hospital and physicians affiliated groups.

Additionally, we found that some carriers, through pricing, force small businesses to take a pre-set benefit or networks. We have found that changing networks can be very disruptive to employees and their families (and company administration). Changing a network might require a participant to find new doctors and go to hospitals that they are unfamiliar with. In designing our benefits we try to the extent possible to minimize disruptions to our associates' choice of providers.

We were faced with increasing cost, less choice, multiple plans and a whole bunch of administrative problems managing the programs. Today's health care system is largely a pass though of all costs to employers and individual participants/insureds.

We have learned that sometimes an insurance carrier will ''buy market share'' by offering low prices to new groups and then dramatically increase premiums or change the benefits on renewals. When an insurer ''buys a market'' through price discounts, it often chases competition out of the market thus allowing the insurer to later increase prices without opposition.

As most small businesses can attest, in a year following any significant claim(s), it becomes virtually impossible to switch providers or to receive competitive quotes at renewal. Even with competition, in the regions where we have operations, we find they are dominated by only two large carriers; thus limiting our choices because both carriers were expensive, only one was more so.

Consolidation in Southwest Ohio

We have a large number of associates in Southwest Ohio (Cincinnati and Dayton, areas). Once there were a number of independent physician practices and independent hospitals. Over the past 15 years, through several consolidations, we found that Dayton's five primary hospitals became essentially two through affiliations (excluding Children's Medical Center).

For more than a year recently, one major hospital in Dayton (and the physicians who maintained privileges only at that hospital) refused to accept the pricing the larger of only two regional health insurers was demanding. So, the two entities parted ways. Our associates living in the neighborhoods surrounding that hospital were forced to find new doctors and use new hospitals on the other side of town. Our choices and those of other small businesses during that year were further reduced because the other big regional health insurer did not cover a major portion of the geographic region in which our employees lived. As employers, we faced the additional disruption that employees go through when they were forced to use new doctors and hospitals outside their own neighborhoods.

In Cincinnati a similar thing happened. 13 Hospitals became 3 through affiliations (excluding Children's). In both regions physician practices were purchased, consolidated and affiliated with one of the large hospital affiliated groups and now they are large enough to stand up to the insurers in the area and resist pricing pressures.

Throughout Southwest Ohio, the few large hospital and affiliated physician groups have been successful at increasing their prices by threatening to again ''kick out'' one or both of the only two very large regional health insurance companies that wanted discounts or reduced increases. This was at the expense of the employees of small businesses in the entire area that have been forced to pay the higher rates. Small businesses lack the necessary clout to use against either the medical providers or insurers.

The message remains the same, small businesses' choices are reduced and prices are increased without any meaningful competition. The market today for small business health insurance is essentially ''take it or leave it.''

Don't Underestimate the Impact of Discriminatory Underwriting in the Small Business Market

Another phenomenon that we now face is that our insurance carriers engage in *discriminatory* pricing and/or coverages. In years when our associates and their families were generally healthy our premiums rose consistent with reported national average increases. However, in recent years we've had some associates with serious health problems. In the case of our fully insured plans, our premiums have increased well beyond the national averages and we have been unable to get competitive insurers to quote the group. (Examples of serious health problems include: organ transplants, heart problems, cancer, stroke, aneurysms, premature childbirth and conditions that can be treated with very expensive drugs such as MS (Victory has seen pharmaceuticals costing as much as $20,000 per month).

In our self-insured health plans, our excess insurers would simply delete the ill participant from our group (it's called ''lasering out'' a patient or condition). For example, the premium for our excess insurance would still increase. In addition, the carrier would tell Victory that we would have to cover the first $50,000 or $75,000 of a particular individual's health costs. Again, while we might get quotes from excess carriers, we found that they all generally behave the same as it relates to individuals facing serious health problems. I would describe this concept as insurance companies only wanting to insure healthy groups.

One of Victory's smaller businesses has a number of older associates with many of the ailments that go along with age and they are paying a higher premium than any of our other groups. This particular business employs fewer than 20 associates and it is stuck with our incumbent regional carrier. Whenever we can get quotes from carriers willing to quote this group, they are always higher, or exclude afflicted associates or they adjust the benefits to include unreasonable limitations on benefits—such as a 40% co-payment on non-formulary brand name drugs without any cap. If an associate has MS and their medications costs $5,000 month, 40% would be $2,000 a month. That cost is simply not affordable so the treatment is discontinued or less effective treatments are used.

We have found that even former associates electing coverage under COBRA can and do have an impact on health insurance costs if the individual has a serious health condition. Former associates who have existing medical problems often find they have no choice but to continue with coverage under COBRA because they are unable to obtain affordable health insurance elsewhere. Consolidation in the industry has compounded the problem, by reducing the number of available insurers to whom an individual can even apply for coverage.

Another unexplained phenomenon is that if a group is turned down or priced by one carrier at a premium, it seems like every other carrier in the region somehow learns of this which makes it more difficult to find alternatives.

Victory has also seen a number of conflicts in the industry that are generally hidden from its insureds. For example one of our PPO networks receives undisclosed payments from the doctors and hospitals that are subscribers. When we inquired as to why they received these payments, and whether these payments were passed though to Victory by way of discounts, we were unable to get an answer. It was strongly suggested by

our broker not to push the issue. Are these payments made to keep the network from demanding deeper discounts? What about hospital and treatment centers that are owned by physicians. Why are these arrangements hidden? In the end they can stifle competition, cost and choice.

Victory's experience is that the health insurance industry covertly or otherwise discriminates against small business and individuals that have significant health problems. Small businesses have no market power or advocate for the wrongful conduct, so large and powerful regional health insurance and hospital/physician affiliates stand to lose nothing by engaging in this conduct.

How do small businesses control health care costs today?

Unfortunately this proves to be an exercise of the lesser of a number of evils, few that the small business can control. Each year at our annual health insurance renewals, we get a quote from our broker that first shows the price of keeping the same health benefits for the upcoming year. From an employer standpoint this is the least disruptive to the employees and their families (and business administration). Unfortunately, in our experience, this usually includes a cost increase. So our broker then offers a series of options to either keep the cost the same as the previous year or reduce the increase in cost for the upcoming year. These options include:

- Increasing the amount of premium that each associate pays;
- Increasing co-payments and/or deductibles;
- Impose charges on unhealthy lifestyles, such as smoking or obesity premiums;
- Reduce and/or eliminate benefits;
- Modifying benefits and provide financial incentives (or disincentives as the case may be) to use modified benefits [1];
- Be very selective in hiring employees—*i.e.* hire only healthy employees [2];
- Incorporate a Health Savings Account or Health Reimbursement Account into the plan design (higher deductible and lower benefits); and/or
- Eliminate offering employer provided health insurance.

Conclusion

Historically small businesses make up the backbone of our nation's employers. Collectively small businesses employ the largest number of people in the U.S. Yet, because each company is small, we have almost no market clout to help bring changes into the health care system. For improvements we must depend on you in the Congress.

Reduced competition in health care at the insurer level or the provider level has increased the costs of health care to Victory and its employee-associates as well as those of other small businesses. Solutions must include some meaningful competition. Pooling and sharing of risks without selective health screening, will advance competitive pricing. Keeping a multiple payer and provider system gives greater flexibility to experiment and discover ways to improve our health care system, A single payor or socialized plan will put all of our nation's eggs in one basket, which certainly disfavors innovation and experimentation. On paper our present system should work, but because of inefficiencies and gaming, it doesn't.

Victory appreciates the Committee on Small Business review of this important issue and the opportunity to present its views on the topic. We thank you for the invitation to present our views. We hope that the Committee and U.S. Congress will take our comments along with the comments from fellow panel members and others, seriously and not make this just another political battle without substantive change. Small business and the tens of millions of their employees, and your constituents will suffer.

The problems are complex and involve a large number of interested parties; political pressure will be exerted by the well-funded. Let's work toward a solution and show the world that we can not only put humans on the moon, but we have the intelligence and creativity to fix a broken, expensive and complex system of delivering health care.

Testimony of Greg Scandlen, President, Consumers for Health Care Choices

''Health Insurer Consolidation: The Impact on Small Business''
Committee on Small Business, United States House of Representatives
October 25, 2007.

Madam Chairman, and Members of the Committee,

Thank you for the opportunity to share some thoughts with you today about the problems created by excess concentration in the health insurance market.

I am Greg Scandlen. I am the founder and president of Consumers for Health Care Choices, a national, non-profit and non-partisan membership organization with members in 44 states. I have been in health policy since 1979 when I was hired by Blue Cross Blue Shield of Maine to rewrite their contracts in plain language. I spent 12 years in the Blue Cross Blue Shield system, including 8 years with the national association where I was responsible for state government relations, including being liaison with the National Association of Insurance Commissioners, National Governors' Association, National Conference of State Legislatures, and other organizations of state officials.

I left the Blues in 1991 to organize a trade association of smaller insurance companies, the Council for Affordable Health Insurance. I ran that organization for five years and left to become a consultant and a researcher for several national think tanks.

I applaud this committee for its long-standing interest in the health insurance market, especially for small employers. For many years surveys have shown there is no greater issue weighing on the minds of small business owners, but now we are seeing that the issue has gone from being a worry of business owners to a crisis in health policy as fewer employers are able to offer coverage at all. The latest Kaiser Family Foundation survey (available at *http://www.kff.org/insurance/7672/index.cfm*) found that the percentage of the smallest employers (with 3–9 employees) offering any coverage has dropped from 57% in 2000 to 45% today.

This fall-off of enrollment is usually attributed simply to rising costs, but I think it is deeper than that. I think both employers and employees look at the health insurance market and find products and services that are over-priced, inefficient, unaccountable, inconvenient, and incomprehensible. They simply do not find value here and they don't see many available alternatives.

This indifference to customer needs and preferences is characteristic of non-competitive markets. Vendors see little need to innovate, cut costs, improve services, or simplify processes because everyone else is offering the exact same product at the exact same price. Customers are stuck.

The Consequences of Excessive Regulation

This non-competitive market is not an accident of history and it is not inherent in health insurance. I was closely involved in the small group reform efforts of the NationalAssociation of Insurance Commissioners (NAIC) in the late 1980s. I knew the commissioners and the staff of the committees that developed the NAIC's model laws and regulations quite well, and they were very explicit about their intentions. They said at the time the reforms they were proposing would do nothing to lower costs or increase access. All they wanted to do was ''stabilize the market.'' In their view, the small group market was suffering from an excess of competition that was confusing to purchasers. They thought it would be better if there were only three or four competing companies in each state.

They have been wildly successful. In my state of Maryland there are now just two companies controlling 90% of the small group market. Options are few and prices are high. Individual coverage is a far better deal in Maryland, and in most other states, than small group coverage. That is part of the reason small employers are dropping group coverage—they and their employees can get a better deal with individual insurance.

The regulations imposed on the small group market included some that were later made industry-wide by Congress when it enacted HIPAA. but also a host of other regulations that discouraged participation in this market—rating restrictions, underwriting restrictions, minimum participation and employer contribution requirements, bans on list billing, standardized benefit designs, requirements on provider participation,

[1] For example, last week in our annual health insurance renewal, our broker suggested that we encourage our associates to have elective surgical procedures performed overseas. We were advised that even paying for travel for two, treatment and recovery at what was described as Four Seasons like heath care facilities that cater to westerners; we would save tens of thousands on elective surgical procedures. We were informed, for example, that a single knee replacement that costs approximately $30,000 in the Midwest would cost under $5,000 inclusive of travel for two in Singapore. Victory is not ready to mandate its associates travel thousands of miles and away from their families and loved ones to obtain health care, however it is difficult not to seriously consider the potential savings.

[2] Victory doesn't engage in, support or condone this practice; however, we understand that the practice is not uncommon.

claims approval and claims review requirements, capitalization and reserve requirements, investment restrictions, minimum loss-ratio standards, market conduct requirements, and of course, state-mandated benefits.

All of these regulations, however well-intentioned, add to the cost of coverage. Moreover, many carriers found it expensive and difficult to comply with all the varying requirements of many different states, especially as the requirements changed from year to year. As a consequence, many carriers decided to get out of the health business and sold off their blocks of business to larger carriers who could afford the compliance costs. This is the primary cause of concentration in this market.

Is Concentration a Good Thing?

Now, some people will argue that this concentration is a good thing, but these arguments are based on a poor understanding of insurance markets. Let me explain.

Risk Pooling

People often argue that the purpose of insurance is to pool risks, so the bigger the carrier, the better. Too much competition, they say. ''segments the market'' and loses the benefit of the pooling mechanism.

Risk pooling is indeed an essential function of insurance, but all of the benefits of pooling are achieved with a relatively small number of people. The optimal size of a risk pool is frequently debated among actuaries and depends on a host of factors (See, for instance, *www.sonoma-county.org/health/ph/mmc/pdf/models.pdf*), but most of the beneficial effects of pooling can be achieved with as few as 25,000 covered lives. It is simply not the case that bigger pools are better.

Economies of Scale

Similarly, people argue that bigger is better to achieve economies of scale. Fixed costs can be spread across a larger population, lowering the cost to each individual.

Again, the argument is valid—as far as it goes. But at a certain point there will also be dis-economies of scale and managerial inefficiency. Where that point is, is open to debate. The graphic below is taken from *Risk Pooling in Health Care Financing: The Implications for Health System Performance*, by Peter C. Smith and Sophie N. Witter, both of the Centre for Health Economics at the University of York, York, UK, and published by the World Bank in 2004 (available at *http://extsearch.worldbank.org/servlet/SiteSearchServlet?q=risk%20pooling*).

It illustrates two things:

1. The advantage of risk pooling levels off at a certain number of covered lives;

2. There are substantial dis-economies of scale beyond a certain number.

QuickTime™ and a TIFF (LZW) decompressor are needed to see this picture.

Adverse Selection

Finally, people will argue that having a wide selection of health coverage choices invites ''adverse selection,'' that is, people of like-risks will segment themselves into different health plans, with the healthiest going into one with minimal benefits and the sickest going into the one with the richest benefits. They say it would be fairer to allow only rich benefits so that the healthy will subsidize the preferences of the ill.

Certainly selection happens but it can be manageable, as we have seen with FEHBP. Plus, the flip side of adverse selection is moral hazard. If it is true that high-risk people will select the richest benefit programs, it is also true that low-risk people who are placed into rich benefits programs will use more health care services than they otherwise would, raising the costs of coverage for all. In either case, the presence of insurance distorts normal consumer behavior. ''Fairness'' is not served by forcing people to purchase benefits they have no use for, and that is one of the reasons so many small employers are not buying coverage at all.

Innovation Needed

These criticisms all assume that there is a single type of health insurance coverage that is most suitable for all people, but as Clark Havighurst and his colleagues at the Duke Law School have found, the type of comprehensive coverage that is most common today is aimed at the well-educated elite and is in fact subsidized by lower-income working people who derive little value from the coverage. In a recent special edition of *Law and Contemporary Problems*, (available at *http://www. law.duke.edu/journals/journaltoc?journal=lcp&toc=lcptoc69autumn2006.htm).* Mr. Havighurst says, ''lower-income insureds get less out of their employer's health plans than their higher-income coworkers despite paying the same premiums.'' He argues that over-regulation prohibits the offering of more modest benefit packages that would have greater appeal to the same lower-income workers who have little ability to influence the regulators. He adds that the current system ''greatly amplifies price-gouging opportunities for health care firms with monopoly power.''

One exception to this situation has been the introduction of Health Savings Accounts (1–ISAs), a very modest innovation that appeals to some segments of the market that did not find value in comprehensive coverage. By some measures, between 30 percent and 40 percent of the non-group and small group purchasers of HSAs were previously uninsured (see, for example, *HSAs and Account-Based Plans: An Overview of Preliminary Research*, 6/28/2006, available at *http://www.ahipresearch.org/*), suggesting that they did not find value in the comprehensive plans that used to be the only option.

But HSAs are only one small example of the potential for innovation in the benefits market. Another can be found within the Medicare program. Medicare's Special Needs Plans (SPNs) have had very promising success in designing benefits specifically for subsets of beneficiaries, such as people with chronic conditions. (See, for example, *Managed Healthcare Executive*, ''Medicare Advantage Plans establish SNPs to provide care to dual eligibles, high-risk patients,'' *http://mhe.adv100.com/mhe/article/articleDetail.jsp?id=322943*). This is a major departure from conventional practice where health plans typically try to avoid high-risk people with costly conditions. These Special Needs Plans welcome them and design benefits for them that will lower the cost of their care.

Another potential innovation was designed by a recently deceased member of my organization, James Pendleton, MD. The ''Pendleton Plan'' (available at *http://www.chcchoices.org/articles.html*) is aimed at costly hospital inpatient care. It is like a Schedule of Allowances benefit structure based on average hospital costs in an area, but it also includes graduated co-payments or rebates if the patient chooses a facility that is more or less expensive than the average. This plan has not yet been brought to market, but several insurers are interested in it and may try it out on a demonstration basis.

I am familiar with several other entrepreneurs who are working on unique benefit designs and trying to raise the capital to turn these ideas into reality. But they are discovering very significant barriers to entry in the small group market imposed by the regulatory system. They are likely to focus instead on the large group market that has relatively few regulatory barriers at this time.

Creating a More Competitive Market for Small Group Coverage

There is a lot that has to be done to restore competition in health insurance. Anti-trust enforcement is one aspect, and my organization was concerned enough about the recent United/Sierra merger in Nevada to ask the Department of Justice to reject the merger. In our letter to the Attorney General (March 26, 2007) we wrote:

We have no opinion about the companies themselves. Whether they are good or bad or something in between is irrelevant to us. The question to us is solely whether this merger increases or decreases competition and consumer choice. This is the same standard we would apply to any other merger proposal, between hospitals, between pharmaceutical manufacturers, or any other aspect of the health care system.

Consumers need more choices, not fewer. There is already far too much concentration in the hands of a few giant players in health care. Greater concentration means less competition and that is bad for consumers.

Indeed, concentration is rife throughout the health care system with mergers of not only insurers, but hospitals and pharmaceutical companies as well.

The health plans will argue they need to become more concentrated to deal with the rising concentration of these other actors. But hospitals argue they need to merge to deal with the rising concentration of the carriers. It is a spiral that is quickly leading to near-monopolization throughout health care, to the detriment of individual consumers.

Anti-trust action can forestall the most egregious of these mergers, but anti-trust does not create new competitors or encourage innovation if the artificial barriers to entry are high and the regulatory environment unfavorable, Indeed, anti-trust cannot prevent a company from going out of business in an unprofitable climate.

We also do not expect many states to relax their regulatory burdens. Some have, but it is

unusual for legislatures to admit errors and repeal laws. Plus, most of these regulations have constituencies that will tight to retain them. These constituents often include the remaining health plans that enjoy their near-monopoly position and do not want to encourage new competitors.

That leaves only two courses of action for Congress.

1. Allow the interstate purchase of health insurance. States would continue to regulate their domestic carriers, but buyers would be able to purchase coverage from any licensed carrier in the United States. Congressman John Shadegg sponsored legislation (H.R. 2355) in the last Congress to do just this. Small business owners would be able to purchase coverage according to, not only the reputation and integrity of the insurance company, but also the set of regulations that apply to it.

2. Create an alternative federal charter that carriers could choose to operate within. This would be like the current banking system where banks can choose to be state chartered or federally chartered. A state chartered insurance company would be confined to operating within that state, but a federally chartered company could operate anywhere within the United States.

In either case, Congress would restore the intent of the interstate Commerce Clause of the Constitution, which vested the regulation of interstate commerce solely in Congress. Congress ceded its authonty to the states in 1946 when it enacted the McCarran-Ferguson Act, but there is no reason Congress cannot reclaim some or all of that authority, as it did when it enacted ERISA in 1974.

Conclusion

The small group market for health insurance has become dysfunctional over the past twenty years. Excessive regulations, though well-intentioned, have resulted in oligopoly conditions that have led to higher prices, poorer services, and very few choices.

Consumer choice is meaningful only when there is a wide variety of products, services, and vendors from which to choose. We desperately need vigorous competition throughout the health care system to restore market discipline and encourage innovation.

Congressional remedies are limited, but are needed because the states have failed to get the job done.

Statement of Consumer Federation of America, Consumers Union, and US PIRG

To the Committee on Small Business, United States House of Representatives, Regarding Health Insurer Consolidation
October 25, 2007.

Consumer Federation of America, Consumers Union, and US PIRG (''consumer groups'') appreciate the opportunity to present our views to the Committee on Small Business on health insurer consolidation. We commend the Committee for holding this hearing and for its efforts in identifying ongoing conduct that may harm the competitive marketplace. This hearing puts a spotlight on issues critical to consumers and small businesses throughout the United States. An unabated flood of health insurance mergers has led to highly concentrated markets, higher premiums, and lower reimbursement. Skyrocketing premiums have put insurance out of reach for millions of consumers and the number of uninsured Americans has increased to critical levels: over 89 million or one out of three Americans under age 65.[1] As consumers have suffered from egregious deceptive and anticompetitive conduct by insurance companies, those companies have recorded record profits. The problems presented could not be more stark or have a more severe impact on consumers.

In the past decade there have been over 400 health insurer mergers and in only two cases has the Department of Justice brought any enforcement action. The Justice Department has not brought any cases challenging anticompetitive conduct by health insurers, even though numerous private plaintiffs and State Attorneys Generals have challenged this type of conduct. In effect, the insurance companies have gained a newly found ''antitrust immunity.''

The consequences of lax enforcement for consumers are clear. The American Medical Association reports that 95% of insurance markets in the United States are now highly concentrated and the number of insurers has fallen by just under 20% since 2000. These mergers have not led to benefits for consumers: instead premiums have skyrocketed, increasing over 87 percent over the past six years. Patient care has been compromised by the over-aggressive efforts of supposed managed care, and the number of uninsured Americans has reached record levels.

A vital component to assuring the competitive marketplace is protecting the ability of consumers to choose between alternatives. Antitrust enforcement against anticompetitive mergers and exclusionary conduct is essential to a competitive marketplace. This unprecedented level of concentration and the lack of antitrust enforcement pose serious policy and health care concerns. As Vermont Senator Patrick Leahy observed in Hearings before the Senate Judiciary Committee last year on health insurance consolidation:

> a concentrated market does reduce competition and puts control in the hands of only a few powerful players. Consumers—in this case patients—are ultimately the ones who suffer from this concentration. As consumers of health care services, we suffer in the form of higher prices and fewer choices.[2]

Congress is currently grappling with the severe problems of the uninsured. The number who have been uninsured for some period in any two year period has increased by over 17 million since 2001 and now amounts to over 89 million Americans. The reason is simple: the cost of health insurance has outstripped the pocketbooks of both consumers and small businesses.[3] Premiums for both job-based and individual health insurance have risen rapidly over the past seven years and have increased by double-digit amounts annually since 2001. Moreover, these rising premiums have far outstripped increases in worker earnings. Between 2000 and 2006, premiums for job-based health insurance increased by 73.8 percent, while median worker earnings rose by only 11.6 percent.

There is a direct relationship between the insurance consolidation and the anticompetitive conduct engaged in by health insurers, and the increasing problem of the uninsured in the United States. Increased concentration and a lack of enforcement has led to skyrocketing premiums, higher deductibles and higher co-pays. The most severe problems occur simply when employers or employees can no longer afford insurance. Increasingly employers have been forced to scale down insurance or drop insurance altogether. Thus, the number of uninsured individuals has hit a record level. The lack of enforcement has created an environment where the insurance companies act as if they are immune from antitrust scrutiny. This must be reversed.

As a first step, some of us have recommended that the Antitrust Division of the Department of Justice carefully scrutinize United Healthcare's acquisition of Sierra Health, which, if approved, will lead to a virtual monopoly in various health insurance markets in Las Vegas. We have attached a statement of the Consumer Federation of America before the Nevada Commissioner of Insurance on the United Healthcare/Sierra Health merger, which articulates the types of problems posed by increasing consolidation in the health insurance industry.

Again, we welcome the attention of the Committee to this important issue.

Testimony of David Balto, on Behalf of the American Antitrust Institute and Consumer Federation of America

Before the Nevada Commissioner of Insurance on the United Health Group Proposed Acquisition of Sierra Health Services[1]
(July 27, 2007)

I. Introduction

The American Antitrust Institute (''AAI'') and Consumer Federation of America, (''consumer groups'') appreciate this opportunity to testify before the Commissioner of Insurance on United Health Group's (''United'') proposed acquisition of Sierra Health Services, Inc. (''Sierra'').[2] As

[1] See *Wrong Direction: One out of Three Americans are Uninsured* (Families USA 2007).

[2] Statement of Senator Patrick Leahy, Hearing on ''Examining Competition in Group Health Care'' U.S. Senate Committee on the Judiciary (Sept. 6, 2006).

[3] Families USA study at fn 1.

[1] I have practiced antitrust law for over 20 years, primarily in the federal antitrust enforcement agencies: the Antitrust Division of the Department of Justice and the Federal Trade Commission. At the FTC, I was attorney advisor to Chairman Robert Pitofsky and directed the Policy shop of the Bureau of Competition. Maria Patente, Washington College of Law (Class of 2008), provided extensive assistance in the preparation and research of the testimony.

[2] The American Antitrust Institute is an independent Washington-based non-profit education, research, and advocacy organization. Its mission is to increase the role of competition, assure that competition works in the interests of consumers, and challenge abuses of concentrated

Continued

detailed in our testimony based on our preliminary review we strongly believe that this acquisition will harm all Nevada health insurance consumers, particularly those in Clark County, through higher prices, less service, and lower quality of care. The level of concentration posed by this merger is simply unprecedented: it is far greater than in any merger approved by the Antitrust Division of the U.S. Department of Justice (''DOJ'') and would give United clear monopoly power in Clark County.

In evaluating this merger under NRS 692C.210(1) the Commissioner of Insurance must consider several factors including: (1) whether ''the effect of the acquisition would be substantially to lessen competition in insurance in Nevada or tend to create a monopoly'' and (2) whether if approved the ''[a]cquisition would likely be harmful or prejudicial to the members of the public who purchase insurance.'' As we explain below, both of these factors counsel for denial of the application. The merger creates a dominant insurer, particularly in Clark County, with the ability to raise premiums, reduce service and quality and reduce compensation to providers. It will clearly harm purchasers of insurance who will pay more for service that provides lower quality care.

This unprecedented level of concentration raises important policy and health care concerns relevant to the factors evaluated in these Hearings. As Vermont Senator Patrick Leahy observed in Hearings before the Senate Judiciary Committee last year on health insurance consolidation:

a concentrated market does reduce competition and puts control in the hands of only a few powerful players. Consumers—in this case patients—are ultimately the ones who suffer from this concentration. As consumers of health care services, we suffer in the form of higher prices and fewer choices.[3]

Creating a dominant insurance provider should be a profound concern in Nevada, a state plagued with shortages of nurses, doctors and other health care professionals.

This testimony, which is based solely on public information, provides our preliminary views that this merger would ''substantially lessen competition in insurance in Nevada or tend to create monopoly'' and ''would likely be harmful or prejudicial to the members of the public who purchase insurance.'' This paper also addresses the United-Sierra merger in the context of the numerous competitive imperfections and market failures unique to the HMO and health insurance industry and with respect to the specific challenges facing Nevada's health care due to a serious shortage of doctors and nurses.

II. Summary

The consumer groups urge the Commissioner to focus on the following issues:

• ***Will the United-Sierra merger reduce competition for the provision of health insurance to employers and individuals seeking health coverage in Nevada?*** Yes. Sierra is the largest HMO provider in Nevada and United is the only significant rival. The United-Sierra merger in Nevada would give United an 80% market share of all HMOs in Nevada and a 94% market share of the HMO market in Clark County. Although its market share is smaller than Sierra's, United has the potential for significant growth in Nevada since its acquisition of PacifiCare in 2005. Moreover, the next largest HMO rival in Clark County has only a 2% market share. The merger would adversely affect a wide range of buyers including small employers, governmental and union purchasers.

• ***Will the United-Sierra merger reduce competition for the provision of services in the Medicare Advantage program?*** Yes. Medicare is increasingly turning to a managed care model. Increasingly Medicare beneficiaries are signing up for the Medicare Advantage program which provides health care services to beneficiaries in a managed care model. The only current bidders for Medicare advantage in Nevada are United and Sierra. United is the largest Medicare Advantage program in the U.S. The merger would create a monopoly in the provision of services for Medicare Advantage program resulting in a lower level of care and higher prices.[4]

• ***Could the United-Sierra merger increase the threat of monopsony power and reduce access to medical care and the quality of medical care in Nevada?*** Yes. There is currently a significant and chronic shortage of health care providers including physicians and nurses in Nevada, an understaffed region where health professionals are forced to work overtime, double-shifts, weekends, and holidays. This merger will exacerbate those problems for health care providers dependent upon the merged firm. A combined United-Sierra can reduce compensation resulting in a diminution of service and quality of care. In the past the DOJ has brought enforcement actions because of concerns over monopsony power where the market share exceeded 30%, a level clearly exceeded by this acquisition. This merger may lead to a significant reduction in reimbursement for health care providers, leading to lower service and quality of care.

• ***Will other insurance companies readily enter the market (or expand) and fully restore the competition lost from the merger?*** No. In some cases it may be unnecessary to challenge a merger if other firms can readily enter a market to a sufficient degree to avert the anticompetitive effects of the merger. That is clearly not the case for this market. As the DOJ has recognized in other cases, barriers to entry in the HMO market are extremely high due to the extensive physician networks, technology networks, and specialized medical infrastructure that are essential to the industry. Moreover, Nevada already faces a serious shortage of both doctors and nurses, and attracting a sufficient number of personnel would pose a high barrier for a new entity interested in providing HMO plans in Nevada. There has been little historical entry into the Nevada HMO market, in spite of the growth of population. Moreover, with a dominant United-Sierra, it is highly unlikely a new entrant would undertake the risk of new entry.

• ***Do the efficiencies from the United-Sierra merger outweigh the anticompetitive harms?*** No. The parties have not proposed significant efficiencies from this consolidation. If there were any efficiencies they probably could be achieved through internal growth, considering the rapid population growth in Nevada. Moreover, efficiencies should only be included in the competition calculus if they will result in lower prices or better service to consumers. As a general matter, efficiencies from health insurance mergers have not been passed on to consumers. Health insurance mergers have generally led to increased subscriber premiums without expansion of medical benefits. There is little evidence if any that any efficiencies achieved in the United-PacifiCare merger have resulted in lower premiums or better service for United or former PacifiCare subscribers. Since the combined United-Sierra would have a dominant market share post-merger it is highly unlikely any savings would be passed on to consumers.

• ***Would a divestiture or other structural relief be sufficient to alleviate the competitive problems raised by the merger?*** No. The parties have not suggested that they would be willing to divest assets to solve the competitive concerns raised by the merger. Even if they did the Commissioner should be extremely skeptical of any proposed relief. In the past the DOJ has attempted to resolve competitive concerns over some mergers by requiring the divestiture of a certain number of contractual arrangements in order to spur new entry. These divestitures have been insufficient to cure the competitive problems posed by those mergers. A divestiture is even less likely to resolve the competitive concerns in this merger where the merged firm will clearly be the dominant insurer in the market.

• ***Would consumers be better off if the Commissioner rejected the merger?*** Yes. The ultimate antitrust question in evaluating

economic power in the American and world economy. For more information, please see *www.antitrustinstitute.org.* This testimony has been approved by the AAI Board of Directors. A list of contributors of $1,000 or more is available on request. The Consumer Federation of America (''CFA'') is the nation's largest consumer-advocacy group, composed of over 280 state and local affiliates representing consumer, senior citizen, low income, labor, farm, public power and cooperative organizations, with more than 50 million individual members. CFA represents consumer interests before federal and state regulatory and legislative agencies and participates in court proceedings. CFA has been particularly active on antitrust issues affecting health care.

[3] Statement of Senator Patrick Leahy, Hearing on ''Examining Competition in Group Health Care,'' U.S. Senate Committee on the Judiciary (Sept. 6, 2006).

[4] A large number of the consumer complaints filed with the Commissioner about this merger raise concerns over the loss of competition in the Medicare Advantage market. Many of these complaints are from elderly beneficiaries who are particularly vulnerable to anticompetitive conduct. Over 30% of Nevada Medicare beneficiaries subscribe to Medicare Advantage, one of the highest enrollments of any state.

any merger is what would happen ''but for'' this merger? What would happen to the merging parties, consumers, and providers? The answer in this case seems rather transparent. United and Sierra are both successful, financially sound, capable companies that would continue to grow and thrive. Through its acquisition of PacifiCare, United established an important beachhead in Nevada. But for this merger, United would continue to expand in Nevada and challenge Sierra's strong position in the market. That competition between United and Sierra would lead to lower premiums, greater innovation and better service. There is simply no reason why United can not achieve most of the benefits of this acquisition through internal growth.

The remainder of the testimony is set forward as follows. First, we make some observations about special considerations for health insurer mergers and suggest why regulators and enforcers can not rely on the theoretical assumptions of a competitive market. Then we focus on past enforcement actions and the principles of antitrust enforcement. We then explain how the merger will reduce competition in both the provision of certain health insurance products (impact on buyers) and health care providers (impact on sellers). Finally, we explain why other factors such as ease of entry or efficiencies will not prevent the anticompetitive effects of the merger.

III. Antitrust Merger Standards and Past Antitrust Enforcement Actions

The U.S. antitrust laws, like the Nevada insurance statute, provide that a merger may be illegal if it may ''tend substantially to lessen competition or to tend to create a monopoly.'' [5] The concern under the merger laws is that a merger may tend to reduce competition and lead to higher prices, lower service, less quality, or less innovation. Concerns over a reduction in quality, central to the delivery of health care services, is an important element of competition.[6] As the Supreme Court has observed, competition protects ''all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost.'' [7]

In order to determine the likely competitive effects of a merger the case law and the Merger Guidelines established by the Department of Justice and the Federal Trade Commission set forth a multi-step process.[8] The process begins by defining the ''line of commerce'' or relevant product market and the ''section of the country'' or relevant geographic market. A relevant market can include any group of products or services. Once a relevant market is defined, the level of concentration and market share is calculated to determine the likely competitive effects of the merger. In cases where there is an undue level of concentration in the relevant market (generally a market share over 30%) there is a prima facie case of illegality and a presumption of unlawfulness.[9] If there is a presumption of unlawfulness then the burden shifts to the defendants to rebut the prima facie case and demonstrate that other market characteristics make the presumption of anticompetitive effects implausible. Two types of evidence are prominent in merger cases—if the defendants can offer evidence that entry is relatively easy, that may dispel the notion that the merger will lead to significant anticompetitive effects. Finally, if a merger will lead to substantial efficiencies, these may counteract those anticompetilive effects.

The two most instructive antitrust cases involving health insurance mergers are the DOJ's challenges to Aetna's 1999 acquisition of Prudential and United's 2006 acquisition of PacifiCare. Both of these mergers were resolved with divestitures to facilitate the entry of a new competitor to remedy the competitive concerns. Each case focused both on the harm to purchasers of HMO and other insurance services from the exercise of monopoly power and the harm to healthcare providers from the exercise of monopsony power.[10] In both the United-PacifiCare and the Aetna-Prudential mergers, the DOJ identified highly concentrated markets that were substantially likely to suffer harm to competition as a result of these mergers.

In 1999, the DOJ and the State of Texas settled charges that the merger between Aetna and Prudential in the State of Texas would harm competition. The DOJ focused on relevant markets of HMO products and physician services. Aetna and Prudential were head to head competitors in the HMO markets in Houston and Dallas. The proposed merger would have increased Aetna's market share from 44% to 63% in Houston and 26% to 42% in Dallas.[11]

Moreover, the merger raised monopsony concerns by giving the merged firm the potential to unduly suppress physician reimbursement rates in Houston and Dallas, resulting in a reduction of quantity or degradation of quality of medical services in the areas.[12] The operative question from DOJ's perspective was could health care providers defeat an effort by the merged firm to reduce provider compensation by a significant amount, *e.g.*, 5%. The question was answered in the negative for several reasons: physicians have limited ability to encourage patients to switch health plans, and physicians' time (unlike other commodities) cannot be stored, which means that physicians incur irrecoverable losses when patients are lost but not replaced. To exacerbate matters, contracts with physicians were negotiated on an individual basis, and were therefore susceptible to price discrimination by powerful buyers. Thus, DOJ concluded that Aetna had sufficient power to impose adverse contract terms on physicians, especially decreased physician reimbursement rates, which would ''likely lead to a reduction in quantity or degradation in the quality of physicians' services.'' [13]

To resolve these competitive concerns the DOJ ordered Aetna to divest its entire interest in NYLCare-Gulf Coast and NYLCare-Southwest, its Houston and Dallas commercial HMO business. This consisted of 260,000 covered lives in Houston and 167,000 covered lives in Dallas.

[5] Clayton Act. 15 U.S.C. § 18. There is no case law evaluating the competitive legality of mergers under NRS 692C.210(l), however the language of the statute is identical to the Clayton Act. Thus, it is appropriate to apply the standards of federal antitrust law. The Nevada antitrust statute is similar to the Clayton Act. It prohibits mergers that will ''result in the monopolization of trade or commerce * * * or would further any attempt to monopolize trade or commerce'' or ''substantially lessen competition or be in restraint of trade'' NRS 598A.060(l(f).

[6] Section 7 prohibits anticompetitive reductions in quality because it equivalent to an increase in price—consumers pay the same (or greater) price for less. *Community Publishers. Inc.* v. *Donrey Corp.*, 892 F. Supp. 1146, 1153 n.8 (W.D. Ark. 1995), *aff'd sub nom. Community Publishers, Inc.* v. *DR Partners*, 139 F.3d 1180 (8th Cir. 1998); *Merger Guidelines*, § 0.1 (''Sellers with market power also may lessen competition on dimensions other than price, such as product quality, service, or innovation.''); id. § 1.11.

[7] *Nat'l Soc'y of Prof Eng'rs* v. *United States*, 435 U.S. 679,695 (1978).

[8] U.S. Dept of Justice and Federal Trade Comm'n, *Horizontal Merger Guidelines* (1997) (hereinafter ''*Merger Guidelines*''), The Nevada statute provides that in determining whether to approve a merger the Commissioner of Insurance ''shall consider the standards set forth in the Horizontal Merger Guidelines * * * NRS 692C.256(2).

[9] Concentration in merger cases is expressed in terms of market shares and a measure known as the Herfindahl Hirschman Index (''HHI''). The HHI is calculated by adding together the squares of the market share of individual competitors in the market. In a market with a single seller, the HHI is 10,000. The FTC/DOJ Merger Guidelines provide that an HHI below 1000 corresponds to an ''unconcentrated'' market; an HHI between 1000 and 1800 corresponds to a ''moderately concentrated'' market, and a HHI above 1800 corresponds to a ''highly concentrated'' market. The HHI is a screening tool used to assess whether a proposed merger will lead to anticompetitive consequences. Under the Guidelines different presumptions apply, depending on the extent of post-merger market concentration and the increase in HHI that will result from the merger. The greatest competitive concerns are raised where the post-merger HHI exceeds 1800. In such as case, it s ''presumed that mergers producing an increase in the HHI of more than 100 points are likely to create or enhance market power or facilitate its exercise,'' *Merger Guidelines*, § 1.51.

[10] Health insurers play dual roles as sellers of insurance services and buyers of health care services. In its first role, the health insurer's ''output'' consists of health benefit packages, and the output prices are paid for by customers in the form of subscriber premiums. In the role as the seller of health benefits, a dominant health insurer in a concentrated market could potentially act as a ''monopolist'' charging an above market price for health benefits. In its second role, the health insurer acts as a buyer, and the inputs consist of physician and other medical services. The insurer's input prices are the compensation it pays in the form of physician fees and fees for medical services. In this role, the health insurer may act as a ''monopsonist,'' reducing the level of services or quality of care by reducing compensation to providers. Health insurers are both buyers of medical services and sellers of insurance (to consumers), so insurance mergers can raise both monopsony and monopoly concerns.

[11] These market shares are substantially smaller than the market shares which would result from the United-Sierra merger in the HMO markets of Nevada and Clark County (80% in Nevada and 94% in Clark County).

[12] *United States* v. *Aetna*, Revised Competitive Impact Statement, Civil Action 3–99CV1398–H.

[13] *Id.*

In 2006, the DOJ investigated the merger between United and PacifiCare and focused on potential competitive concerns in relevant markets for commercial health insurance for small group employers in Tucson, Arizona and physician services in both Tucson and Boulder, Colorado.[14] Small group employers are employers with 2–50 employees. The merger would have combined the second and third largest providers of commercial health insurance in Tucson and increased United's market share from 16% to 33%.

The merger also raised concerns over the potential harm to competition in the purchase of physician services in both Tucson and Boulder. The DOJ explained that by combining United and PacifiCare ''the acquisition will give United the ability to unduly depress physician reimbursement rates in Tucson and Boulder, likely leading to a reduction in quantity or degradation in the quality of physician services.'' [15] In other words the DOJ found that a health plan's power over physicians to depress reimbursement rates can be harmful to patients—the ultimate consumers of health care. The market shares involved were relatively modest: in excess of 35% in Tucson and in excess of 30% in Boulder ''for a substantial number of physicians in those areas.''

In response to the potential harm to competition, the DOJ required United to divest contracts covering at least 54,517 members residing in Tucson, Arizona to yield a post-merger market share equal to its pre-merger market share. Furthermore, the DOJ required United to divest 6,066 members covered under its contract with the University of Colorado. This divesture constituted nearly half of PacifiCare's total commercial membership in Boulder.

The antitrust laws protect not only consumers but any group of buyers, potentially including a governmental buyer. Buyers of health insurance services have varying needs and ability to secure competitive rates. An example of this is a case filed by the City of New York challenging the merger between Group Health Incorporated (''GHI'') and the Health Insurance Plan of Greater New York (''HIP'') in the fall of 2006.[16] There are numerous health insurance competitors, including HMOs and PPOs in the New York City market, but for the low cost product required by the City and affiliated entities the only rivals were GHI and HIP. The case alleged that the merger of GHI and HIP would create a monopoly in the New York metropolitan area market for low cost health insurance purchased by the City of New York and its employee unions together with the city's employees and retirees as well as 35 other employers with ties to the city and their employees and retirees such as the Housing Authority, the Metropolitan Museum of Art and universities (all of which participate in the New York City health benefits program). The case alleges that city employees and retirees and those individuals who participate in the health benefits program would be faced with increased costs for insurance and reduced service if the merger were consummated. Litigation in the case is ongoing, but it suggests the broad range of markets that can be adversely affected by a merger.

IV. Special Information Concerns for Health Insurance Mergers

In determining the competitive effect of a merger the crucial issue is the impact on the consumer, the ultimate beneficiary of the insurance system. The questions to be examined include will consumers have to pay more for insurance in higher premiums or deductibles, will they suffer from poorer service such as longer waiting times or deterred services, and will they suffer from lower quality of care? Since consumers can not vote on a merger,[17] how does the Commissioner, antitrust enforcer, or the courts evaluate the impact of a merger on consumers? Insurance companies, employers, unions and buyers of insurance (''plan sponsors''), and health care providers will all have views of the impact of the merger on consumers. The views of the insurance companies can not be determinative, since they have an obligation to their stockholders to maximize profits.

The views of plan sponsors are relevant, but their failure to object to a merger may not be of significant evidentiary value. Plan sponsors represent the interests of their subscribers and thus may be concerned with the exercise of monopoly power leading to higher premiums. However, as antitrust authorities have recognized in many merger investigations, buyers of services may be very reluctant to complain about a merger for a variety of factors. They may simply pass on higher post-merger prices to the ultimate customer. In the health insurance area, although plan sponsors may be concerned about the cost of health insurance they may be less sensitive to the reduction in quality or service that may result from a merger. Finally, a customer may fear retribution postmerger.[18] This may particularly be the case in Nevada where the acquired firm will remain as the largest insurer even if the merger is denied. Thus, the fact that plan sponsors do not complain, or actually support a merger, should not be determinative of a merger's likely competitive effect.[19]

On the other hand healthcare providers may be a far more superior representative of the consumer interest and their concerns deserve careful attention. Physicians and other healthcare providers directly experience the diminution of service and quality when so-called cost containment efforts go too far. Physicians serve as advocates for the patient, especially in the often adversarial setting of managed care. Since health care providers experience first hand the impact of reductions in service they are more sensitive to the potential exercise of market power by health insurance. It is important to recognize in evaluating the concerns raised by providers that they are not just complaining about decreased compensation. Rather the issues raised by health care providers are central to concerns over quality of care: reduced services, greater waiting times, unacceptably short hospital stays, postponed or unperformed medical treatments, suboptimal alternative medical treatments, laboratory tests not performed, and other output restrictions on health services.

IV. Competitive Analysis of the United-Sierra Merger

Health Insurer Concentration: Harm To Buyers

The concentration of the health insurance industry has increased nationally due to a tremendous number of mergers and acquisitions and numerous smaller insurers exiting the industry.[20] Over the past 10 years there have been over 400 health insurer mergers. United has acquired several firms including California-based PacifiCare Health Systems, Inc., Oxford Health Plans, and John Deere Health Plan, increasing its membership to 32 million. Similarly, WellPoint, Inc. now owns Blue Cross plans in 14 states. Together, WellPoint and United control over 33 percent of the U.S. commercial health insurance market.

This increase in concentration has not benefited consumers. Studies indicate that health insurance premiums have increased at a rate more than twice the rate of inflation or the rate of increases in worker's earnings. Average annual premium increases have ranged from 8.2% to 13.9% since 2000,[21]

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[14] *United States* v. *UnitedHealth Group Inc.*, Case No. 1:05CV02436 (D.D.C. Dec. 20, 2005), available at *http://www.usdoj.gov/atr/cases/f213800/213815.htm.*

[15] *United States* v. *UnitedHealth Group*, Competition Impact Statement at 8, available at *http://www.usdoj.gov/atr/cases/f215000/215034.htm.*

[16] *City of New York* v. *Group Health Inc., et al.,* (S.D.N.Y. 2006).

[17] Fortunately, the Commissioner has decided to hold an extensive series of hearings on the merger and provided a significant opportunity for public comment. The majority of the public comments filed by consumers to date oppose the merger.

[18] There are a wide variety of reasons why customer support of a merger may not be particularly probative. *See* Ken Heyer, Predicting the Competitive Effects of Merger by Listening to Buyers, 74 Antitrust L.L. 87 (2007); Joseph Farrell, Listening to Interested Parties in Antitrust Investigations: Competitors, Customers, Complementors, and Relativity, Antitrust, Spring 2004 at 64 (explaining why customers may support an otherwise anticompetitive merger).

[19] In several cases courts have enjoined mergers even where customers testified in support of the merger. *See FTC* v. *H.J. Heinz Co.*, 246 F.3d 708 (D.C. Cir. 2001) (customers strongly supported merger); *United States* v. *United Tote*, 768 F. Supp. 1064, 1084–85 (D.Del. 1991) (enjoining merger despite testimony of ''numerous buyers'' that the merger would be procompetitive in creating a stronger rival to a dominant firm); *United States* v. *Ivaco*, 704 F. Supp. 1409, 1428 (W.D. Mich. 1989) (all testifying customers supported merger); *FTC* v. *Imo Indus.*, 1992–2 Trade Cas. (CCH) § 69,943, at 68,559 (D.D.C. 1989).

[20] Victoria Colliver, ''Insurer's Mergers Limiting Options: Health Care Choices Are Narrowing Says Study by AMA,'' San Francisco Chronicle, April 18, 2006 (last viewed 7/8/07) *http://sfgate.com/cgi-bin.article.cgi?file=/chronicle/archive/2006/04/18/BUGUQIAH161.DTL&type=business*

[21] Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits: 2006 Summary of Findings,* 2006 (last viewed 7/8/

Moreover, since 2000, the number of employers offering health coverage benefits has decreased by nearly 10%. Studies indicated that medical benefits have not expanded despite premium increases. In contrast, health insurer profits have increased by 246% in the aggregate over the past decade.[22]

Consumers in highly concentrated health insurance markets are most vulnerable to insurance premium increases without comparable benefit increases, mirroring data of escalating health costs on the national level. One study found that more than 95% of Metropolitan Statistical Areas (MSAs) had at least one insurer in the combined HMO/PPO market with a market share greater than 30% and more than 56% of MSAs had at east one insurer with market share greater than 50%.[23] In concentrated MSAs such as these, there is a much greater likelihood that one firm, or a small group of firms, could successfully exercise market power and profitably increase prices or decrease compensation leading to less quality or service. As one prominent health care professor has observed in testimony before the U.S. Senate Judiciary Committee:

What is so important about the sheer number of competitors? Econometric evidence shows that in the managed care field, an increase in the number of competitors is associated with lower health plan costs and premiums; conversely, a decrease in the number of competitors is associated with increases in plan costs and premiums. The evidence also shows that the sheer number of competitors exerts a stronger influence on these outcomes than does the penetration level achieved by plans in the market.[24]

As we discuss below, the health insurance markets in the state of Nevada, especially Clark County are highly concentrated, and the merger of Sierra with United is likely to substantially harm competition and consumers.

Harm to Competition in Nevada From the United-Sierra Merger

Correctly defining an economically meaningful market is essential for ensuring that consumers of that market do not become subject to market power due to increases in market concentration and decreases in competition as a result of a merger. The key question in this merger as in other mergers is the definition of the relevant product market. The courts have held that a relevant product market ''must be drawn narrowly to exclude any other product to which, within reasonable variation and price, only a limited number of buyers will turn.'' *Times-Picayune Pub. Co.* v. *United States,* 345 U.S. 594, 612 n.31 (1953). Market definition focuses on demand substitution facts, and whether or not consumers would or could turn to a different product or geographic location in response to a ''small but significant non-transitory increase in price.'' [25] Typically, the antitrust agencies and the courts have implemented this test by seeking to identify the smallest group of products over which prices could be profitably increased by a ''small but significant'' amount (normally 5 percent) for a substantial period of time (normally one year).[26]

In health insurance mergers the DOJ has reached different, although not inconsistent. conclusions as to the relevant product market, For example, in the Aetna-Prudential merger DOJ concluded that the relevant product markets were the sale of health maintenance organization (''HMO'') and HMO-based point of service (''HMO-POS'') health plans. The DOJ noted that HMO and HMO-POS products differ from PPO or other indemnity products in term of benefit design cost and other factors. HMOs provide superior preventative care benefits, place limits on treatment options and generally require the use of a primary care physician ''gatekeeper.'' PPO plans are not structured in that fashion and do not emphasize preventative care. HMOs were perceived as being better devices to control costs and configure benefits. In addition, both the insurers and buyers of insurance services perceived PPOs and HMOs as being separate products. Thus, the DOJ concluded that the elasticity of demand for HMO's and HMO-POS plans are sufficiently low that a small but significant price increase for these plans would be profitable because consumers would not shift to PPO and other indemnity plans to make the increase unprofitable.

In United/PacifiCare, the DOJ defined a relevant product market as the sale of commercial health insurance to small group employers. This market consisted of employers with 2–50 employees. These employers were particularly susceptible to potential anticompetitive conduct because they lacked a sufficient employee population to self-insure and they lacked the multiple locations necessary to reduce risk through geographic diversity. In addition the manner in which commercial health insurance was sold also distinguished the small and large group markets. Large employers were more likely than smaller employers to be able to successfully engage extensive negotiations with United and PacifiCare.

We believe that both an HMO and small employer market may be adversely affected by the United-Sierra merger.[27] Surveys demonstrate that consumer do not perceive HMOs and PPOs as substitute products and consumers believe that they differ in terms of benefit design, cost, and general approaches to treatment.[28] PPOs tend to provide more flexibility in selection of physicians and specialists and tend to be more expensive. In contrast, HMOs focus more on preventative medicine but limit treatment options and require referrals from a ''gate keeper'' for many procedures. Consumers with special health needs and those relying more on strong relationships with their physicians would generally not he satisfied if forced to subscribe to an HMO with restrictions on personal choices. ''A small but significant price increase in the premiums for HMOs and HMO-POS plans would not cause a sufficient number of customers to shift to other health insurance products to make such a price increase unprofitable.'' [29]

Moreover, small employers are less likely to have significant alternatives in response to a price increase by the merged firm. Small employers are unable to self-insure and have little power to negotiate better rates.

The relevant geographic market seems to be a fairly straightforward matter since health care services are primarily local. From the perspective of the buyers of insurance services, employers want insurance where the employees work and live. Thus in Aetna/Prudential, the DOJ concluded ''the relevant geographic market in which HMO and HMO–POS plans compete are thus generally no larger than the local areas within which HMO * * * enrollees demand access to providers. * * * As a result, commercial and government health insurers—the primary purchasers of physician services—seek to have their provider network's physicians whose offices are convenient to where their enrollees work or live.''

In this merger the likely geographic markets are Clark County, Nevada, and the larger geographic market of the State of Nevada. Consumers faced with an increase in prices for HMOs are unlikely to travel a long distance away from homes or places of business to in order to escape price increases and purchase HMO services at a lower price. Generally, consumers are reluctant to travel lengthy distances when they are sick. Moreover, virtually all managed care companies provide networks in localities where employees live and work, and they compete with the other local networks.[30] Thus, we believe the proper relevant markets are the provision of HMO services in Clark County and Nevada.[31]

2007) *http://www.kff.org/insurance/7527/upload/7528.pdf*

[22] Laura Benko, ''Monopoly Concerns: AMA asks Antitrust Regulators to Restore Balance,'' Modern Physician, June 1, 2006.

[23] Edward Langston, ''Statement of the American Medical Association to the Senate Committee on the Judiciary United States Senate: Examining Competition in Group Health Care,'' Sept. 6, 2006 (last viewed 7/8/07) *http://www.ama-assn.org/amal/pub/upload/mm/399/antitrust090606.pdf.*

[24] Testimony of Professor Lawton R. Burns re the Highmark/Independence Blue Cross Merger, before the Senate Judiciary Committee (April 7, 2007).

[25] According to the Merger Guidelines,''[a] market is defined as a product or group of products and a geographic area in which it is produced or sold such that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future seller of those products in that area would likely impose at least a 'small but significant nontransitory' increase in price, assuming the terms of sale of all other products are held constant.'' *Merger Guidelines* § 1.0.

[26] *FTC* v. *Staples,* 970 F. Supp. at 1076 n.8; *Merger Guidelines* § 1.11, at 5–6.

[27] Defining the market in terms of a single product is appropriate since the Nevada statute provides that the Commissioner can deny a merger application if she ''determines that an acquisition may substantially lessen competition *in any line of insurance* in this state or tends to create a monopoly.'' NRS 692.258(1).

[28] *See United States* v. *Aetna,* Revised Complaint Impact Statement, Civil Action 3–99CV1398–H (N.D. Tex, 1999).

[29] *Id.*

[30] *Id.*

[31] As to the market for the sale of health insurance products to small employers we have no reason to

Continued

Concentration and Competitive Effects

Once the market is defined antitrust authorities and the courts calculate market shares and concentration levels (using the Herfindahl-Hirschman index (HHI)). This merger will lead to an unprecedented level of concentration. In the Clark County HMO market United's market share will increase from 14 to 94%. If PPOs are included, United's market share increases from 9% to 60%. Regardless of how the product market is defined United is clearly a dominant firm, far larger than the post merger market shares of the combined Aetna/Prudential or United/PacifiCare in those markets where DOJ brought enforcement actions. Even in a Nevada HM0 market, the market share increases from 12% to 80% and in a Nevada HMO–PPO market United's market share increases from 7% to 48%. Simply put, post-merger United will be a dominant firm no matter how the market is defined.

Measuring concentration using the HHI leads to similar results. The Merger Guidelines define a market with an HHI over 1800 as ''highly concentrated'' and an increase over 100 is ''likely to create or enhance market power or facilitate its exercise.'' The post-merger HHI for HMOs in the state of Nevada is 4,871 and the post-merger increase in HHI is 1,625. The HM0 market in Clark County is even more concentrated, with a post-merger HHI of 8,884 and a post-merger increase in HHI of 2,235. These exorbitantly high HHIs support the presumption that a merger between the two largest HMOs in the highly concentrated Nevada HMO market would likely create or enhance market power or facilitate its exercise. The market share data obtained form the Nevada State Health Division is provided below, (Figure 1).

Figure 1. Market Share Data for the HMO Market in Nevada and Clark County.[32]

Nevada			Clark County		
HMO	# patients	Market Share	HMO	Members	Market Share
Sierra Health Plan	279,679	68%	Sierra Health Plan	267,274	80%
United PacifiCare	48,196	12%	United PacifiCare	47,242	14%
Aetna	9,108	2%	Aetna	8,296	2%
WellPoint	11,365	2.70%	Nevada Care	10,639	3%
Hometown Health	23,281	6%	WellPoint	1,297	0.05%
Saint Mary's Healthfirst	27,411	7%	Total	334,748	99%
NevadaCare	10,827	2.60%			
Total	409,867	100%			

The Nevada and Clark County markets are highly concentrated, no matter how defined. The parties may suggest that this is of little import because the increase in concentration is not substantial because United currently has a relatively modest market share. Such an argument is inconsistent with the facts and the law. United is the largest health insurer in the United States and the second largest rival in the market, with the ability and incentive to expand competition. As to the law as the Supreme Court has acknowledged, ''if concentration is already great, the importance of preventing even slight increases in concentration is correspondingly great.'' [33]

As important, the combined United-Sierra will be substantially larger than its next closest rival. In the Nevada HMO market it will be over 10 times larger (80% to 7% for the second largest firm) and in the Clark County market it will be over 30 times larger (94% to 3%). The courts have recognized that smaller rivals are far less likely to constrain the conduct of a dominant firm post-merger, and have enjoined mergers with far smaller disparities in market share. *United States* v. *Phillipsburg Nat'l Bank,* 399 U.S. 350, 367 (1970) (merged firm three times the size of next largest rival): *FTC* v. *PPG,* 798 F.2d 1500, 1502–03 (D.C. Cir. 1986) (two and one-half times as large). Where a merger produces a firm that is significantly larger than its closest competitors, it increases the likelihood that the firm will be able to raise prices, decrease compensation, and reduce quality without fear that the small sellers will be able to take away enough business to defeat the price increase. *See United States* v. *Rockford Mem. Corp.,* 898 F.2d 1278. 1283–84 (7th Cir.) (Posner, J.), cert. denied, 498 U.S. 920 (1990); H. Hovenkamp, *Federal Antitrust Policy* § 12.4c (1993) (''markets may often have small niches or pockets where new firms can carve out a tiny position for themselves without having much of an effect on competitive conditions in the market as a whole'').

Combined PPO and HMO Markets

Using a definition of the health insurance product market as the combination of HMOs and PPOs, the health insurance market in Nevada is highly concentrated, and the United-Sierra merger would substantially increase the likelihood of competitive harm.

The market share for Sierra and United combined in Nevada is 48%, while in Clark County the combined United-Sierra market share is 60%. The post-merger HHI for the Nevada and Clark County markets are 3372 and 5244. respectively. The increase in the HHI market resulting from the United-Sierra merger is 555 for the state of Nevada and 921 for Clark County. Data of market shares from the Nevada State Health Division for the HMO and PPO markets is provided in Figure 2.

believe the concentration measures differ significantly from the HMO market.

[32] Data provided from the Nevada State Health Division.

[33] *United States* v. *General Dynamics Corp.,* 415 U.S. 486, 497 (1974).

[34] Data from the Nevada State Health Division.

[35] The market share for WellPoint in Clark County is overstated because in the absence of data by territory, all WellPoint customers were allocated to Clark County.

Figure 2. Market Share Data for the HMO/PPO Market in Nevada and Clark County.[34]

Nevada			Clark County [35]		
Insurance Firm	Members	% Market Share	Insurance Firm	Members	Market Share
Aetna Health Inc.,	9,108	1.18%	Sierra	297,825	51.35%
Sierra Health	312,702	40.67%	WellPoint	231,971	39.99%
WellPoint	231,971	30.17%	United	50,210	8.66%
Hometown Health	99,189	12.90%	Total	580,006	100.00%
NevadaCare	20,331	2.64%			
United Pacific Care	52,456	6.82%			
Saint Mary's Health First	43,141	5.61%			
Total	768,898	100.00%			

Conclusion on the Impact of the United-Sierra Merger on Consumers

As the U.S. Supreme Court has held where a merger results in a significant increase in concentration and produces a firm that controls an undue percentage of the market, the combination is so inherently likely to lessen competition substantially that it ''must be enjoined in the absence of evidence clearly showing that the merger is not likely to have such anticompetitive effects.'' *United States* v. *Philadelphia Nat'l Bank,* 374 U.S. 321, 363 (1963). The United-Sierra merger clearly raises extraordinary and unprecedented levels of concentration which raise serious concerns about this merger. Nevada is in need of greater competition, not less. Further consolidation among the limited health plan providers in Nevada poses a substantial threat of harming customers, increasing the costs of health care, and decreasing access to quality health care and the quality of health. This merger clearly ''would likely be harmful or prejudicial to the members of the public who purchase insurance'' and thus should be denied.

V. Health Insurance Concentration: Harm to Health Care Professionals and Quality of Care

The nature of the health care industry facilitates the potential for a dominant health coverage or insurance firm to exercise market power (or monopsony) over individuals selling health care services within a geographic region. Because medical services can be neither stored nor exported. health care professionals generally must sell their services to buyers (insurance firms and their customers) in a relatively small geographic market. Refusing the terms of the dominant buyer, physicians may suffer an irrevocable loss of revenue. Consequently, a physician's ability to terminate a relationship with an insurance coverage plan depends on her ability to make up lost business by switching to an alternative insurance coverage plan. Where those alternatives are lacking a physician may be forced to reduce the level of service in response to a decrease in compensation.

Not all insurance providers are equal from the perspective of a health care provider. A smaller insurance company with fewer covered lives may not be an attractive alternative. Health care providers who depend on an insurance program for all or most of their income are at a substantial disadvantage when there are not competing programs available; when they switch programs, they tend to lose the patients who have that particular coverage. It makes little sense for a provider to switch to an insurer who has a substantially smaller market share because there won't be enough patients to sustain the practice. Thus, it is critical for insurance regulators to maintain a competitive market in which health care providers have significant competitive alternatives.

In the Aetna/Prudential and United/PacifiCare mergers, the DOJ raised monopsony concerns in markets for purchasing physicians services where the market shares were far less substantial than they are in Clark County. For example, in United/PacifiCare the DOJ alleged that the combined firm would account for an excess of 35% in Tucson and over 30% in Boulder.

In addition, it is important to recognize that it may be appropriate to prevent a firm from securing monopsony power even if it faces a competitive downstream market. In other words there may be antitrust concerns if a health insurer can lower compensation to providers even if it can not raise prices to consumers. For example, in United/PacifiCare the Division required a divestiture based on monopsony concerns in Boulder even though United/PacifiCare would not necessarily have had market power in the sale of health insurance. The reason is straightforward—the reduction in compensation would lead to diminished service and quality of care, which harms consumers even though the direct prices paid by subscribers do not increase.[36]

Underlying the monopsony analysis in these cases is the premise that physicians who have a large share of reimbursements from the merged firm lack alternatives in response to a reduction in compensation. As alleged in Aetna, they cannot retain or timely replace a sufficient portion of those payments if the physicians stop participating in the plans. Moreover, it is difficult to convince patients to switch to different plans.[37]

Consequently. according to the Division these physicians would not be in a position to reject a ''take it or leave it'' contract offer and could be forced to accept low reimbursement rates from a merged entity, likely leading to a reduction in quantity or degradation in quality of physician services.

The merging parties may suggest that there is some safe harbor for mergers leading to a market share below 35%. As the DOJ enforcement action in Boulder demonstrates, that is not the case. The unique nature of health care provider services explains why monopsony concerns are raised at lower levels of concentration than may be appropriate in other industries. If a health care provider's output is suppressed by a reduction in compensation, then it is a lost sale that cannot be recovered later. Physician services can not be stored for later sale. As the DOJ observed in United/PacifiCare: ''A physician's ability to terminate a relationship with a commercial health insurer depends on his or her ability to replace the amount of business lost from the termination, and the time it would take to do so. Failing to replace lost business expeditiously is costly.'' [38] The DOJ observed that there are limited outlets for physician services: ''There are no purchasers to whom physicians can sell their services other than individual patients or the commercial and governmental health insurers that purchase physician services on behalf of their patients.'' [39] As a former DOJ official observed ''these factors explain why the Department concluded that shares below 35 percent, in the particular markets at issue, sufficed to allege competitive harm.'' [40]

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[36] See Marius Schwartz, Buyer Power Concerns and *Aetna-Prudential Merger,* Address Before the Annual Health Care Antitrust Forum at Northwestern University School of Law 4–6 (October 20. 1999) (noting that anticompetitive effects can occur even if the conduct does not adversely affect the ultimate consumers who purchase the end-product), available at *http/www.usdoj.gov/atr/public/speeches/3924.wpd.*

[37] As alleged in the *United* complaint, physicians encouraging patients to change plans ''is particularly difficult for patients employed by companies that sponsor only one plan because the patient would need to persuade the employer to sponsor an additional plan with the desired physician in the plans's network'' or the patient would have to use the physician on an out-of-network basis at a higher cost. Complaint at paragraph 37.

[38] Complaint at paragraph 36.

[39] Complaint at paragraph 33.

[40] Mark Botti, Remarks before the ABA Antitrust Section, ''Observations on and from the Antitrust Division's Buyer-Side Cases: How Can ''Lower'' Prices Violate the Antitrust Laws.'' He also noted that: ''Physicians have a limited ability to maintain the business of patients enrolled in a health plan once the physician terminates. Physicians could retain patients by encouraging them to switch to another health plan in which the physician participates. This is particularly difficult for patients employed by companies that sponsor only

Continued

Again the proponents of health insurance mergers may suggest that regulators should take a benign view about the creation of monopsony power because health insurers are ''buyers'' acting in the interest of reducing prices. As we suggested earlier, this view is mistaken. Health insurers are not true fiduciaries for insurance subscribers. Plan sponsors may have a limited concern over the product based on the cost of the insurance, and not the quality of care. Furthermore, health coverage plans operate in the interest of a group, not in the best interest of individual patients. Consequently, insurance firms can increase profits by reducing the level of service and denying medical procedures that physicians would normally perform based on professional judgment. In the absence of competition among insurers, patients are more likely to pay for these procedures out-of pocket or forego them entirely. Ultimately, the creation of monopsony power from a merger can adversely impact both the quantity and quality of health care.

Finally, the evidence from mergers throughout the U.S. strongly suggests that the creation of buyer power from health insurance consolidation has not benefited competition or consumers. Although compensation to providers has been reduced, health insurance premiums have continued to increase rapidly. Moreover, evidence from other mergers suggests that insurers do not pass savings on from these mergers on to consumers. Rather, insurance premiums increase along with insurance company profits.

Monopsony in the Health Care Markets of Nevada

United's acquisition of Sierra would give it unique control over the physicians serving the HMO and HMO–PPO markets in Clark County and the State of Nevada. The merger will combine the two largest HMOs with an 84% market share in Nevada and a 90% market share in Clark County, dramatically higher than the concentration in any merger approved by the DOJ. In light of these high market shares, a physician faced with unfair contract terms could not credibly threaten to leave the combined United-Sierra health plan, except by departing Clark County.

The parties have suggested the markets for physician reimbursement are far less concentrated. At the earlier hearing they suggested the merged firm would account for only 17% of physician reimbursement in the state and 21% in Clark County. We do not know the basis for the claimed reimbursement percentages. One should take United's estimates of market shares with a large grain of salt. In United/PacifiCare their lawyers suggested the parties' total share of physicians' reimbursements likely were substantially below the 35% threshold, but those estimates were rejected by DOJ. As one of their advocates said ''indeed the parties' calculated their total shares of physician reimbursements in the Tucson and Boulder MSAs were substantially lower than the shares asserted in the complaint.'' [41] The estimates of the proponents in the Aetna/Prudential merger were also rejected by the DOJ.[42]

Monopsony power exercised by HMOs and health insurance plans, like high medical malpractice insurance premiums, has the potential to drive health care professionals out of geographic regions and even into other professions. The Nevada health care market currently faces one of the largest shortages of doctors and nurses in the country.[43] It ranks 49th of the 50 states in physician coverage. Shortages of health care professionals can become a vicious cycle admonishing others against entering the profession. Doctor shortages increase with shortages of nurses and increases in insurance costs.'' [44] Nationally, it has become less attractive to become a physician because of the enormous cost associated with medical education, long years of schooling and residencies, and increased difficulty in earning a living.[45] Recently, Nevada has implemented programs to attract doctors from Mexico and train doctors in Mexico at the Universidad Autonoma de Guadelajara.[46]

Similar problems exist in nursing. Understaffed nursing departments require nurses to work overtime, work more holiday shifts, and undertake more responsibilities. These conditions exacerbate protracted work-related stress and decrease the attractiveness of working as a nurse in Nevada. Moreover, reduced flexibility for time-off and patient dissatisfaction resulting from overworked nurses is generally associated with lower levels of job satisfaction and higher turnover rates.[47]

Conclusion on the Impact on Health Care Professionals and Quality of Care

The United-Sierra merger poses a substantial threat to competition leading to reduced compensation for health care professionals who may be forced to reduce service and quality of care. This reduced quality of care ''would likely be harmful or prejudicial to the members of the public who purchase insurance.'' Further consolidation in the HMO and health coverage markets in Nevada may have detrimental short-term and long-term effects by exacerbating the crisis of the health professional shortage. Competition is essential to the delivery of high quality health care services. The United-Sierra merger will further distort the already concentrated and inefficient Nevada health care market.

Barriers to Entry Are High

As noted earlier, entry can be a factor in the analysis of a merger that may reverse the presumption of anticompetitive effects. The courts have required that ''entry into the market will likely avert the anticompetitive effects from the acquisition.'' *FTC* v. *Staples,* 970 F. Supp. 1066, 1086 (D.D.C. 1997). Entry must be ''timely, likely insufficient in its magnitude. character and scope to deter or counteract the competitive effects'' of a proposed acquisition. Merger Guidelines § 3.0.

The barriers to entry in the HMO and health insurance markets in Nevada and Clark County are very high. There has been relatively little recent entry into either Clark County or Nevada. The fact that United, the largest health insurer in the U.S., chose to enter into Nevada through two acquisitions—PacifiCare and Sierra—suggests the significant difficulty of de novo entry in these markets.

Generally, entry into health insurance markets is difficult. The health care industry does not fit the traditional model of perfect competition as expounded by the Chicago School.[48] For example, there is a high degree of ''lock-in'' because plan sponsors cannot disrupt the medical treatment of countless employee/patients. New entrants are vulnerable to the high switching costs that characterize the health insurance industry. Many consumers have no choice for health coverage plans and must accept the plan provided by an employer. Other consumers can only switch during an ''open enrollment'' season. Doctors cannot easily switch their patients to a different health plan and, in the

one plan because the patient would need to persuade the employer to sponsor an additional plan with the desired physician in the plan's network. Alternatively, the patient may remain in the plan, visiting the physician on an out-of-network basis. The patient would be faced with the prospect of higher out-of-pocket costs, either in the form of increased co-payments for use of an out-of-network physician, or by absorbing the full cost of the physician care.'' Complaint at paragraph 37.

[41] Fiona Schaeffer et al., ''Diagnosing Monopsony and other issues in Health Care Mergers: An overview of the United/PacifiCare Investigation,'' Antitrust Health Care Chronicle (2006).

[42] The estimates of the level of physician reimbursement by the proponents of the Aetna/Prudential merger were also rejected by the DOJ, The proponents suggested that the total amount of physician revenues affected by the merger were far less than thirty percent according to public available data. According to the proponents, the merged firm would have accounted for about 20% of total physician revenues in Houston and about 25% of total physician revenues in the Dallas Fort Worth area after the transaction. In addition, there were 14 HMOs in the Houston area and 12 HMOs in Dallas. *See* Robert E. Bloch et al. ''A New and Uncertain Future for Managed Care Mergers: An Antitrust Analysis of the Aetna/Prudential Merger.'' Yet the DOJ required an enforcement action to address monopsony concerns in spite of these alleged low shares of reimbursement.

[43] *See* Lawrence Mower, ''Help Sought South of the Border,'' Las Vegas Review Journal, Jan. 22, 2007; *see also* Lenita Powers, ''Big Day at Lawlor,'' Reno Gazette, Dec. 9, 2006 (expressing that nurses in Nevada are in a desperately short supply, especially OR nurses).

[44] *See* Lawrence Mower, ''Help Sought South of the Border,'' Las Vegas Review Journal, Jan. 22, 2007.

[45] Lawrence Mower, ''Help Sought South of the Border,'' Las Vegas Review Journal, Jan. 22, 2007.

[46] *Id.*

[47] *See* Jennifer Kettle, *Factors Affecting Job Satisfaction in the Registered Nurse,* Journal of Undergraduate Nursing Scholarship, Fall 2002 (last viewed July 9, 2007) *http://www.juns.nursing.arizona.edu/articles/Fall%202002/Kettle.htm.*

[48] *See* Thomas Greaney, *Chicago's Procrustean Bed: Applying Antitrust Law in Health Care,* 71 Antitrust L.J. 857 n. 1 (2004) (''Perfectly competitive markets demonstrate the following four characteristics: (1) Perfect product homogeneity (2) large numbers of buyers and sellers (3) perfect knowledge of market conditions by all market participants and (4) complete mobility of all product resources.'')

absence of a large number of patients enrolled in a plan, a doctor may find that additional claim processing costs exceed the benefits of carrying an additional health coverage provider. Similarly, doctors may be reluctant to switch plans because earnings lost in pursuit of new patients and alternate third-party payers may lead to exorbitant losses.[49]

Developing an HMO from scratch requires extensive expenditure on recruiting and maintaining health professionals, developing computer information systems and data banks, and high expenditures on overhead and clinical facilities. De novo entry is very challenging since new entrants must develop a reputation and product recognition with purchasers to convince them to disrupt their current relationships with the dominant health insurers.[50] As a recent DOJ/FTC report on health care competition reported, there has been relatively little de novo entry by national health insurers.[51]

Not surprisingly the DOJ has recognized the substantial barriers to entry and expansion in health insurance markets. In the Aetna/Prudential merger, the DOJ found substantial entry barriers. Certainly Dallas and Houston were attractive markets for health insurers. Both markets had a substantial number of alternative health insurers capable of expansion. And there were numerous competitors in other Texas markets that were capable of entering into these markets. Yet the DOJ found substantial entry barriers and that entry could take two to three years and cost up to $50 million.[52] In particular it found that it was ''unlikely that a company that currently provides PPO or indemnity health insurance in either Dallas or Houston would shift its resources to provide an HMO or HMO–POS plan'' in either market.[53]

Entry barriers are even more substantial in Nevada and Clark County. The shortage of health care professionals in Nevada increases barriers to entry because new entrants are unlikely to be able to contract with an adequate number of health professionals to attract new plan sponsors and enrollees. Moreover, when a dominant HMO maintains a high market share, other health providers may perceive or experience higher rates of adverse selection, moral hazard, and general vulnerability to tactics by a dominant HMO to raise rival's costs.[54] Experience indicates that new HMOs have not historically entered highly concentrated markets after a merger occurs.

The parties may also suggest that some of the smaller HMOs and health insurance providers in Nevada may be able to expand post-merger to prevent any anticompetitive effects. This is extremely unlikely because the fringe firms are currently so extremely small and far smaller than a combined United-Sierra. In cases with an even far smaller size disparity between the merged and fringe firms courts have declined to find that small players might suddenly expand to constrain a price increase by leading firms. *United States* v. *Philadelphia Nat'l Bank,* 374 U.S. 321, 367 (1963); *United States* v. *Rockford Mem. Corp.,* 898 F.2d 1278, 1283–84 (7th Cir. 1990) (''three firms having 90 percent of the market can raise prices with relatively little fear that the fringe of competitors will be able to defeat the attempt by expanding their own output to serve customers of the three large firms'').

The small firm expansion claim was rejected by the DOJ in Aetna/Prudential, a case with far smaller post-merger market shares and a far greater number of fringe firms:

> Due not only to these costs and difficulties, but also to advantages that Aetna and Prudential hold over their existing competitors—including nationally recognized quality accreditation, product array, provider network and national scope and reputation—existing HMO and HMO–POS competitors in Dallas or Houston are unlikely to be able to expand or reposition themselves sufficiently to restrain anticompetitive conduct by Aetna in either of these geographic markets.[55]

History demonstrates that one can not rely on new entry in Clark County. Few competitors from the rest of Nevada have been able to successfully enter Clark County. Attempting to enter into a market dominated by a single firm is a daunting task. There may be several obstacles to expansion including cost disadvantages, efficiencies of scale and scope and reputational barriers. In other mergers, the courts have found these types of impediments to be significant barriers to entry and expansion. For example, in the FTC's successful challenge to mergers of drug wholesalers the court noted: ''[t]he sheer economies of scale and scale and strength of reputation that the Defendants already have over these wholesalers serve as barriers to competitors as they attempt to grow in size.'' [56] We believe similar obstacles exist for potential entrants in these markets.

Relying on promises of entry and expansion may be a risky path for competition and consumers. In recent FTC/DOJ health care hearings, a former Missouri Commissioner of Insurance discussed several HMO mergers that his office approved based on the parties' arguments that entry was easy, that there were no capacity constraints on existing competitors (there were at least ten HMO competitors), and that any of the 320 insurers in the state could easily enter the HMO market. Unfortunately, those predictions were mistaken and there has been no entry in the St. Louis HMO market since the mid-1990s.[57] This experience, should make any regulator cautious about relying on predictions of new entry.

Efficiencies of the United-Sierra Merger Are Minimal

The parties have not suggested that there are significant efficiencies that may result from the merger. Under the Nevada statute, the Commissioner can consider efficiencies that either ''create[] substantial economies of scale or economies in the use of resources that may not be created in any other manner'' or ''substantially increase[] the availability of insurance.'' [58] In either case, the public benefit of either of these efficiencies must exceed the loss of competition. This standard simply can not be met in this case where the merger creates a dominant firm.

As a matter of U.S. merger law, efficiencies can justify an otherwise anticompetitive merger in very limited circumstances. Those efficiencies which are considered under the antitrust laws are solely those efficiencies which lead to improvements for consumers in terms of lower prices, greater innovation or greater service and quality. Moreover, an efficiency must be merger specific—that is it can not be achieved in any less anticompetitive fashion. When a cost savings does not result in those benefits to consumers it is not properly considered.

The record on recent health insurance mergers does not suggest that these mergers have led to substantial benefits to consumers in lower prices, better quality of care or service. Despite the occurrence of hundreds of health insurance mergers that have occurred in the past decade, subscriber premiums have continued to rise at twice the rate of inflation and physician fees.[59] Health benefits have not expanded with subscriber premiums.[60] Consequently, the efficiencies

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[49] Moreover, most employee/patients are limited to the physicians within the plan sponsors contract.

[50] At the FTC/DOJ Health Care hearings, a former Missouri Commissioner of Insurance suggested that new entrants ''face a Catch 22—they need a large provider network to attract customers, but they also need a large number of customers to obtain sufficient price discounts from providers to be competitive with the incumbents.'' In addition, he observed that there is a first mover, or early mover, advantage in the HMO industry, possibly resulting in later entrants having a worse risk pool from which to recruit members. He also observed reputation may inhibit entry. *See Improving Health Care: A Dose of Competition,* A Report by the Federal Trade Commission and the Department of Justice, Chapter 6 at 10 (July 2004), *available at http://www.usdoj.gov/atr/public/health_care/204694/chapter6.htm#3.*

[51] *Id.* at 11 (citing testimony that the only successful entry of national plans has been by purchasing hospital-owned local health plans).

[52] In light of the health professional shortage in Nevada, these values could be understated.

[53] Complaint at paragraph 23.

[54] *See* Roger Noll, *Buyer Power and Antitrust: ''Buyer Power'' and Economic Policy,* 72 Antitrust L.J. 589, 2005.

[55] Complaint at paragraph 24. In Aetna, the post-merger market shares were 44% and 62% and there were between 10–12 smaller competitors capable of expansion. In this case, the post-merger market share is greater than 90% and there are a handful of smaller competitors.

[56] *FTC* v. *Cardinal Health, Inc.,* 12 F. Supp. 34, 57 (D.D.C. 1998); *see United States* v. *Rockford Memorial Hosp.,* 898 F.2d 1278. l283–84 (7th Cir. 1990) (''the fact [that fringe firms] are so small suggests that they would incur sharply rising costs in trying almost to double their output . . . it is this prospect which keeps them small'').

[57] Testimony of Jay Angoff, former Missouri Commissioner of Insurance, before the FTC/DOJ Healthcare Hearings, April 23, 2003 at 40–45, discussed at *Improving Health Care: A Dose of Competition,* A Report by the Federal Trade Commission and the Department of Justice, Chapter 6 at 10 (July 2004), available at *http://www.usdoj.gov/atr/public/health_care/204694/chapter6.htm#3.*

[58] NRS 692C.256(3).

[59] Laura Benko, ''Monopoly Concerns: AMA Asks Antitrust Regulators to Restore Balance,'' Modern Physician, June 1, 2006.

[60] Best Wire, ''Study Says Competition in Health Markets Waning,'' Best Wire Apr. 19, 2006.

in health insurance mergers deserve careful scrutiny and a heavy dose of skepticism.[61]

The actual record on efficiencies from health insurance mergers is spotty at best. As Professor Lawton Burns has observed in Congressional testimony:

[T]he recent historical experience with mergers of managed care plans and other types of enterprises does not reveal any long-term efficiencies.

[E]ven in the presence of [efforts to achieve cost-savings] and defined post-integration strategies, scale economies and merger efficiencies are difficult to achieve. The econometric literature shows that scale economies in HMO health plans are reached at roughly 100,000 enrollees. * * * Moreover, the provision of health insurance (e.g., front-office and back-office functions) is a labor-intensive rather than capital-intensive industry. As a result, there are minimal economies to reap as scale increases. * * * Finally, there is little econometric evidence for economies of scope in these health plans—e.g,. serving both the commercial and Medicare populations. Serving these different patient populations requires different types of infrastructure. Hence, few efficiencies may be reaped from serving large and diverse client populations. Indeed, really large firms may suffer from diseconomies of scale.[62]

United's actual record in achieving efficiencies is a mixed one at best. Bigger is not necessarily better and a national platform is not better than a local one. To provide just one example, United completely disrupted efficient working relationships between University Medical Center and PacifiCare by replacing the local insurer's claims processing with a more bureaucratic national one.[63] This disruption in working operations increased the number of unpaid claims and created other problems with provider services. One need look no further than United's track record for inadequate claims processing over the past five years.

- The Nebraska Department of Insurance, which imposed a fine of $650,000, the largest ever, on United Health for inadequately handling complaints, grievance, and appeals.
- In March 2006, the Arizona Department of Insurance fined United $364,750 for violating State law by denying services and claims, delaying payment to providers and failing to keep proper records.
- In December 2005, the Texas Department of Insurance fined United $4 million for failing to pay promptly, lacking accurate claim data reports and not maintaining adequate complaint logs. They also had to pay restitution to physicians.[64]

State imposed fines are an inadequate remedy for poor services to patients and doctors. First, the actual payer of these fines is the consumer, because United can pass these fines on to consumers in the form of higher premiums and co-payments. Second, fines pose no solace to patients that may suffer the persistent hounding from creditors as a result of unpaid insurance claims. Further consolidation will only enhance the likelihood of shoddy claims service since consumers will have few rivals to turn to in response to poor quality of service.

United may suggest the merger is procompetitive because it will lead to improved cost containment initiatives. Of course, Sierra may adopt those measures without a merger. In addition, although efforts to contain costs are rooted in legitimate needs, the actual implementation of cost containment efforts can produce negative consequences for the quality of health care provided to consumers. However, most cost containment efforts center on decreasing utilization. Moreover, in concentrated markets, the likelihood of administered pricing and agreements not to reimburse for a procedure is more likely. Ultimately, the insurer's gross margin increases by reducing access to care and the quality of care for consumers.

The burden should be on the merging parties to demonstrate that the efficiencies they put forward are not speculative, that they exceed the likely anticompetitive effects on consumers and suppliers of services, and that the benefits will be passed on in the form of lower premiums and better quality, rather than larger profits for shareholders. It is highly unlikely that burden can be met in this case.

Recommendations

The United-Sierra merger poses a serious threat to competition in the provision of insurance and health care services in Nevada, especially Clark County. This merger requires heightened scrutiny given the currently high concentration of the health coverage providers in the Nevada market and the current shortage of health care professionals in the State. The merger should be denied because it ''would * * * substantially * * * lessen competition in insurance in Nevada or tend to create and monopoly,'' through the creation of a dominant health insurance provider particularly in Clark County. Moreover, it will lead to a reduction in the level and quahty of service thus harming and prejudicing ''the members of the public who purchase insurance.'' Enhancement of Nevada's health care requires increased levels of competitton and greater market efficiency, which cannot be achieved through a merger between two of the States largest health insurance providers. The likelihood of competitive harms from the United-Sierra merger is substantial, and the procompetitive benefits *de minimus*. Pursuant to NRS 692C.258(l), we urge the Commissioner to deny the merger application.

In the matter of: In the United States District Court for the District of Columbia, United States of America, Plaintiff, v. UnitedHealth Group Incorporated and Sierra Health Services, Inc.; Defendants.

[Civil No. 1:08–cv–00322] Judge: Ellen S. Huvelle. Filed: 2/25/2008.

Comments of the American Medical Association, Nevada State Medical Association and The Clark County Medical Society on the Proposed Consent Order

On February 25, 2008 the Antitrust Division of the Department of Justice filed a complaint and proposed final judgment (''PFJ'') with this Court regarding the acquisition of Sierra Health Services by UnitedHealth Group. Although this acquisition creates a dominant health insurer and permanently transforms the health insurance market for Clark County, Nevada, the DOJ identified a very limited set of competitive concerns in the Medicare Advantage market and proposed a remedy limited to that market.

The American Medical Association, Nevada State Medical Association and the Clark County Medical Society file these comments pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b–e) (known as the ''Tunny Act'') because the DOJ's complaint and PFJ are seriously inadequate to remedy the competitive concerns arising from this transaction. This merger results in United dominating the commercial health insurance market with over a 56% market share. In spite of the substantial level of concentration resulting from this merger, the DOJ chose to challenge the impact of the merger on a single duplicative product, Medicare Advantage. The Justice Department's enforcement action is inadequate in several respects.

- It fails to secure relief in the market for the purchase of physician services;
- It fails to secure relief in the commercial insurance market; and
- It fails to prevent United from using contractual provisions such as most favored nations and all products clauses that may diminish the likelihood that the remedy will fully restore competition. The relief is also inadequate to fully restore competition in the Medicare Advantage market.

Finally, we explain why United's history of regulatory violations should raise significant concerns about relying on its promises to comply with the PFJ.

The DOJ decision not to challenge this acquisition is inconsistent with critical healthcare concerns. As documented in recent Congressional hearings before the Senate Judiciary Committee and the House Small Business Committee there is a tremendous trend of health insurance consolidation, which has led to higher premiums and a greater number of uninsured.[1] The proposed merger faced almost unprecedented opposition from community groups, public interest groups, healthcare alliances, physicians, nurses. employers. and state legislators.[2]

[61] See Laura Benko, ''Bigger Yes, But Better?'' Modern Health Care, March 19, 2007.

[62] Testimony of Professor Lawton R. Burns re. the Highmark/Independence Blue Cross Merger, before the Senate Judiciary Committee (April 7, 2007).

[63] *See* Laura Benko, ''Bigger Yes, But Better?'' Modern Health Care, March 19, 2007.

[64] Marshall Allen, ''Insurer Comes Here With a Trail of Fines From Other States,'' Las Vegas Sun, June 20, 2007.

[1] See testimony from: *Examining Competition in Group Health Care,* Hearing before the Senate Judiciary Committee, 109th Cong. (Sept. 6, 2006), and *Health Insurer Consolidation—The impact on Small Business,* Hearing before the House Small Business Committee, 110th Cong. (Oct. 25, 2007).

[2] For example, see Jennifer Robison, *MERGERS AND ACQUISITIONS:* Buyout sessions conclude. Las Vegas Rev. J. (July 28, 2007). Twenty-four organizations and individuals ranging from doctors and nurses to business owners, spoke out in opposition to the merger at the Nevada Dept. of Ins.

As described herein. the DOJ enforcement action is insufficient to address the critical healthcare and competitive concerns in the market highlighted by the widespread opposition. In spite of the particularly fragile Nevada health care delivery system, DOJ applied an even more lax standard than used in previous mergers and permitted an unprecedented level of concentration clearly in violation of the law and the Merger Guidelines. Ultimately, the Nevada Attorney General had to step in and file a separate case in federal court with 61-page consent order to address some, but not all, of the concerns ignored by the DOJ.[3] The PFJ should be rejected and this matter should be reopened to fully address the competitive concerns raised by this merger.

I. The Interests of the Parties

These comments are submitted on behalf of the American Medical Association, a non-profit professional association of approximately 240,000 physicians, residents, and medical students; the Nevada State Medical Association, and the Clark County Medical Society. The Medical Associations represent the interests of 1,458 doctors in the State of Nevada, and in particular 846 doctors in Clark County. These physicians will be competitively injured from the merger. The merger will result in a dominant health insurance company with the unilateral ability to reduce the level of compensation to physicians and in turn reduce the level of service and quality of treatment that those physicians can provide to patients. In addition, those physicians purchase insurance for themselves and their employees and will have to pay more for insurance because of this merger.

II. Procedural Background

In March 2007 United announced its proposed purchase of Sierra for $2.6 billion. In May, the DOJ issued a ''second request'' under the federal Hart-Scott-Rodino AntitrustImprovements Act of 1976, seeking more information. The state of Nevada conducted a simultaneous investigation.[4]

On February 25, 2008, after an 11-month investigation. the DOJ and Nevada Attorney General's office filed simultaneous, but separate enforcement actions. The DOJ action claimed that the merger would pose significant competitive problems in the Medicare Advantage health insurance market in Las Vegas, Nevada because the merged firm would control 94% of the market. The DOJ alleged this would result in higher prices, fewer choices, and a reduction in the quality of plans purchased by seniors in this area. These concerns were partially addressed within the PFJ which merely requires the divestiture of United's Medicare Advantage business.

Simultaneously, the state of Nevada filed a complaint and decree in federal court in Las Vegas, Nevada. The 61-page Nevada consent order also compelled the divestiture of United's Medicare Advantage business; but went far beyond the DOJ action and addressed competitive concerns involving physicians, Clark County, the University Medical Center and the delivery of healthcare to underserved populations. For example, on physician-related concerns, the Nevada decree enjoins the merging parties from enforcing all products and most favored nations clauses in their contracts for a period of two years, prohibits the merging parties from entering into exclusive contracts with physicians for a period of two years, and creates a Physicians Council for the purpose of addressing the relations between United and physicians, among other relief.

III. The Tunney Act Standards

The Tunney Act requires that ''[b]efore entering any consent judgment proposed by the United States * * *, the court shall determine that the entry of such judgment is in the public interest.'', 16 U.S.C. § 15(e)(1). In applying this ''public interest'' standard the burden is on the government to ''provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *United States* v. *SBC,* 489 F.Supp. 2d 1, 16, (D.D.C. 2007), citing *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1460–61 (D.C. Cir. 1995).

The 2004 Congressional amendments to this Act specifically overruled District of Columbia Circuit Court of Appeals and District Court precedent that was deemed overly deferential to Antitrust Division consent decrees.[5] In response to those decisions, Congress reemphasized its intention that courts reviewing consent decrees ''make an independent, objective, and active determination without deference to the DOJ.''[6] Courts are to provide an ''independent safeguard'' against ''inadequate settlements''.[7] Specifically, the Act was amended to *compel* reviewing courts to consider both ''ambiguity'' in the terms of the proposed remedy, as well as the ''impact'' of the proposed settlements on ''competitors in the relevant market or markets.''[8] Moreover, the 2004 amendments were adopted to highlight that Congress expected an independent judiciary to oversee proposed settlements to ensure that the needs of the consumer were met.

We submit the DOJ has an extra burden to justify the limited relief in this case for two important reasons. First, the DOJ decision not to bring an enforcement action challenging the anticompetitive effects of the merger in the physician services or commercial insurance markets described herein is inconsistent with past enforcement actions such as United/PacifiCare[9] and Aetna/Prudential,[10] in which it required a enforcement policy on health insurance mergers it bears an obligation to disclose the reasons for those changes, so that the court can determine whether entry of the PFJ is in the public interest.

Second, the action taken by the DOJ is inconsistent with the State of Nevada's separate suit challenging the merger in federal court in Nevada. In that action, the Nevada Attorney General secured relief to address some of the substantial concerns raised by the medical associations, consumer groups, Clark County, and public interest groups. The Department's failure to address these concerns in its enforcement action requires heightened scrutiny by this court.

As described herein, the Department's apparent abandonment of its prior enforcement policies and failure to address the concerns recognized by the State of Nevada is especially unfortunate given the national shortage of physicians and the medical market distress that is particularly acute in Nevada.[11] All of these concerns demand the attention of this court.

IV. No Relief in the Market for the Purchase of Physician Services

The DOJ erred in failing to secure relief in the market for the purchase of physician services, even though the merger will significantly increase the level of concentration in that market. The merger will increase United's overall market share in the sale of commercial insurance products to

hearings held July 2007. In addition, there was strong opposition to the merger by consumer groups including Consumers Federation of American and the American Antitrust Institute. See testimony of David A. Balto before the Nevada Commissioner of Insurance on the UnitedHealth Group proposed acquisition of Sierra Health Services, Inc. (July 27, 2007) (appended herein as Attachment C).

[3] *State of Nevada* v. *UnitedHealth Group Inc. and Sierra Health Services, Inc.,* Case No. 2:08–cv–00233 (D. NV 2008).

[4] The Nevada Division of Insurance conducted hearings and approved the merger in August 2007 based on an agreement that United would maintain staffing levels in its local home office, would not pass on acquisition costs to subscribers, and other provisions.

[5] In this matter, the DOJ may claim that the court's review is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the court to go beyond the scope of the complaint. See FR 73, No. 47, at 12774 (March 10, 2008). We believe that view is inconsistent with the legislative history of the 2004 Amendments to the Tunney Act. Congress amended the Tunney Act in 2004 to overrule District of Columbia Circuit Court of Appeals and District Court precedent that was overly deferential to Antitrust Division consent decrees. The amendments to the Tunney Act *compel* the reviewing court to consider, *inter alia,* the ''impact'' of the entry of judgment on ''competition in the relevant market.'' See Pub. L. 108–327, § 221(b)(2) rewriting 15 U.S.C. § 16(e).

No suggestion is made in the statute or legislative history that the courts should defer to either the Government's identification of injury or the Government's proposed remedy to that injury. On the contrary, as one of the authors of the legislation noted, the reviewing court is to achieve an ''independent, objective, and active determination without deference to the DOJ.'' *See* 150 Cong. Rec., S. 3617 (April 2, 2004) (Statement of Sen. Kohl).

For criticism of the overly deferential standard see Darren Bush and John J. Flynn, *The Misuse and Abuse of the Tunney Act: The Adverse Consequences of the ''Microsoft Fallacies'',* 34 Loy. U. Chi. L.J. 749 (2002–2003).

[6] *See* 150 Cong. Rec., S 3617 (April 2,2004) (Statement of Sen. Kohl).

[7] *Id.*

[8] *Id.*

[9] *United States* v. *UnitedHealth Group, Inc.,* Case No. 1:05CV02436 (D.D.C. Dec. 20, 2005) (complaint) [hereafter United/PacifiCare Complaint], available at *www.usdoij.gov/atr/cases/f213800/213815.htm.*

[10] *United States* v. *Aetna, Inc.,* Case No. 3:99CV1398–H (N.D. Tex. June 21, 1999) (complaint) [hereinafter Aetna Complaint], available at *www.usdoj.gov/atr/cases/f2500/2501.pdf.*

[11] *See* Section IX herein.

56%. By combining two of the three largest buyers of physician services in Clark County, the merger poses a significant threat of reducing physicians' compensation and leading to an overall decrease of the level of service provided to patients.

The DOJ has brought enforcement actions on potential concerns over the decrease in competition in the past at market share levels similar or less significant than in this matter. In Aetna/Prudential it required a divestiture where the commercial insurance market shares would increase from 44% to 63% in Houston [12] and 26% to 42% in Dallas [13]. In United/Pacificare it required a divestiture where the commercial insurance market shares increased from 16% to 33% in Tucson [14] and to over 30% in Boulder, Colorado.[15] These enforcement actions were brought even though the defendants alleged much lower market shares in the purchase of physician services markets.

The nature of the health care industry facilitates the potential for a dominant health insurer to exercise monopsony power over physicians selling health care services within a geographic region. Because medical services can be neither stored nor exported, health care professionals have limited options for selling their services to buyers (insurance firms and their customers). If the physicians were to refuse the terms of the dominant buyer, they would likely suffer an irrevocable loss of revenue. Consequently, a physician's ability to terminate a relationship with an insurance coverage plan depends on that physician's ability to make up lost business by switching to an alternative insurance coverage plan. Where, as in the instant case, those alternatives are lacking, a physician may be forced to reduce the level of service in response to a decrease in compensation. Moreover, it is difficult to convince patients to switch to different plans.[16] Consequently, according to the DOJ in past enforcement actions, these physicians would not be in a position to reject a ''take it or leave it'' contract offer and could be forced to accept low reimbursement rates from a merged entity, likely leading to a reduction in quantity or degradation in quality of physician services.

Moreover, the size of the insurer impacts the ability of a physician to leave or credibly threaten to leave a plan. Not all health insurers are equal from the perspective of a physician. To terminate participation in a health insurer, a physician must make up the lost revenue. Smaller plans will offer fewer prospective patients. It makes little sense for a physician to switch to a plan which has a substantially smaller market share because there will not be enough patients to sustain the physician practice. Thus, it is critical for antitrust enforcers to maintain a competitive market in which physicians have adequate competitive alternatives.[17]

These concerns are documented by the affidavit of Professor David Dranove, the Walter McNerney Distinguished Professor of Health Industry Management at the Kellogg School of Management at Northwestern University.[18] Professor Dranove investigated the impact of the United/Sierra merger on the purchase of physician services. Based on the physician survey, consisting of supervising interviews with physicians and his knowledge of healthcare markets, he concludes there is a relevant market for the purchase of physician services in Clark County, Nevada. He further concludes that the merger will pose a substantial risk of harm in that market, and will adversely affect both physicians and consumers.

Professor Dranove posits that perhaps one reason that the DOJ did not seek to remedy potential anticompetitive effects in the market for the purchase of physician services is that the DOJ mistakenly underestimated the monopsony power created by the merger by including Medicare and Medicaid in the relevant market. Physicians can not increase their revenue from Medicare and Medicaid in response to a decrease in commercial medical insurer compensation. Enrollment in these programs is limited to the elderly and disabled and there are only a fixed number of these patients. Moreover, Medicaid pays physicians significantly less than commercial insurance payers. Professor Dranove concludes: ''Medicare and Medicaid do not represent viable alternatives for physicians who face lower fees from a monopsonist insurer. Because Medicare and Medicaid are large purchasers of physician services, excluding them from market share calculations will profoundly change inferences about market shares and monopsony power.[19] Medicare and Medicaid should therefore be excluded when computing shares in the market for the purchase of physician services.

Although the market share information in the market for the purchase of physician services is not publicly available there are proxies that can be used. The shares of the commercial market present a useful proxy of the share in the physician market. Professor Dranove has determined that the market shares in Sierra and United in the Las Vegas metropolitan area (which closely approximates Clark County) were 38% and 18% respectively. The combined market share is 56%. Professor Dranove concludes that this combined share, as well as the increase in share, raises substantial concerns about monopsony power that the DOJ does not appear to have addressed.[20] United/Sierra's combined market share in the commercial market suggests they have a substantial market share in the physician payment market. These market shares are clearly sufficient to raise concerns over the exercise of monopsony power.[21]

Professor Dranove's affidavit and the results of the physician survey demonstrate the potential anticompetitive effects of the merger on the delivery of physician services. As he observes, some physicians would have to cut back on the level of service. Other physicians would consider moving from the market. Other physicians might be forced to see fewer patients. Professor Dranove summarizes the potential harm to consumers:

> Part and parcel with a reduction in the compensation of physicians will be a reduction in the number of physicians who participate in the monopsonist's network. (This is the natural consequence of a monopsonist moving down its upward sloping supply curve.)[22] The patients who previously utilized the services of physicians who are no longer in the network must now either (a) select another, less preferred physician within the network, or (b) see their prior physician out-of-network and consequently pay higher out-of-network fees. Either way, these patients are worse off than before the exercise of monopsony power.

Even the patients of physicians who remain in the United/Sierra network may be

[12] Aetna Complaint at paragraph 22.

[13] *Id.*

[14] United/PacifiCare Complaint at 27.

[15] *Id.* at paragraph 41.

[16] As alleged in the *United/PacifiCare* complaint, physicians encouraging patients to change plans ''is particularly difficult for patients employed by companies that sponsor only one plan because the patient would need to persuade the employer to sponsor an additional plan with the desired physician in the plan's network'' or the patient would have to use the physician on an out-of-network basis at a higher cost. Complaint at paragraph 37.

[17] In most cases, like this one, a firm with monopsony power will also have market power in the downstream market—the sale of commercial insurance so that lower input prices do not lead to lower consumer output prices. See Peter J. Hammer and William M. Sage, *Monopsony as an Agency and Regulatory Problem in Health Care*, 71 Antitrust L.J. 949, 967 (2004). But even if that was not the case, there may be antitrust concerns if a health insurer can lower compensation to physicians even if it can not raise prices to patients. For example, in *United/PacifiCare* the DOI required a divestiture based on monopsony concerns in Boulder even though United/PacifiCare would not necessarily have had market power in the sale of health insurance. The reason is straightforward—the reduction in compensation would lead to diminished service and quality of care, which harms consumers even though the direct prices paid by subscribers do not increase. *See* Gregory J. Werden, *Monopsony and the Sherman Act: Consumer Welfare in a New Light*. 74 Antitrust L.J. 707 (2007) (explaining reasons to challenge monopsony power even where there is no immediate impact on consumers). Marius Schwartz, *Buyer Power Concerns and the Aetna-Prudential Merger*, Address Before the 5th Annual Health Care Antitrust Forum at Northwestern University School of Law 4–6 (October 20, 1999) (noting that anticompetitive effects can occur even if the conduct does not adversely affect the ultimate consumers who purchase the end-product), *available at http://www.usdoj.gov/atr/public/speeches/3924.wpd*.

[18] *See* Dranove Aff. (May 13, 2008), appended herein as Attachment A.

[19] *Id.* at 4.

[20] *Id.* at 4.

[21] For example, in United/PacifiCare the DOJ alleged that the combined firm would account for an excess of 35% of physician reimbursement in Tucson and over 30% in Boulder. Yet in both of these actions DOJ required a divestiture in order to resolve concerns about the potential exercise of monopsony power. In addition, as a former DOJ official explains, the unique nature of health care physician services explains why monopsony concerns are raised at lower levels of concentration than may be appropriate in other industries. Mark Botti, Remarks before the ABA Antitrust Section, ''Observations on and from the Antitrust Division's Buyer-Side Cases: How Can ''Lower'' Prices Violate the Antitrust Laws,'' (April 18, 2007).

[22] When supply is upward sloping, a seller with monopsony power profits by reducing the wages it pays, relative to the competitive wage. By doing so, fewer suppliers offer their goods and services, so that the monopsonist ends up reducing the quantity of output it produces.

worse off, because the reduction in the fees paid to these physicians may cause them to reduce the quantity and/or quality of services they provide* * *

If physicians reduce their office hours, this is likely to affect access for all of their patients. (Physicians who contract with a monopsonist could not normally limit their availability to the monopsonist's patients only.) Similarly, if a physician cuts back on staff and/or equipment, or invests less in continuing education, all patients would surfer. Of course if the physician exits the market altogether, all patients suffer.[23]

The DOJ's failure to oppose the merger suggests that it takes a benign view about the creation of monopsony power. Perhaps the DOJ, like proponents of health insurer mergers, is now taking the view that health insurers are ''buyers'' acting in the interest of reducing prices. As we suggested earlier, this view fails to come to grips with the monopsony issue in any meaningful way and fails to address the reality that patients are the ultimate consumers.[24] As a general proposition, monopsony power does decrease economic welfare. Monopsonists drive down their buying price by purchasing fewer products. Because there is less product purchased, there is, in turn, less product sold.[25] Thus, the reduced input costs of monopsonist medical insurers will not necessarily result in lower premiums to patients and hence elevated levels of consumer welfare. This fact was emphasized by R. Hewitt Pate, the Assistant Attorney General of the Antitrust Division, in a 2003 statement before the Senate Judiciary Committee:

A casual observer might believe that if a merger lowers the price the merged firm pays for its inputs, consumers will necessarily benefit. The logic seems to be that because the input purchaser is paying less, the input purchaser's customers should expect to pay less also. But that is not necessarily the case. Input prices can fall for two entirely different reasons, one of which arises from a true economic efficiency that will tend to result in lower prices for final consumers. The other, in contrast, represents an efficiency-reducing exercise of market power that will reduce economic welfare, lower price for suppliers, and may well result in higher prices charged to final consumers.[26]

Moreover, University of Pennsylvania Health Economics Professor Mark Pauly has demonstrated that health insurers with monopsony power may profit from pushing provider prices ''too low'' so that consumers do not receive an adequate level of service and quality.[27] Also, because health insurer monopsonists typically are also monopolists, lower input prices do not lead to lower consumer output prices.[28]

In any event, health insurers are not true fiduciaries for insurance subscribers. Plan sponsors may have a limited concern over the product based on the cost of the insurance, and not the quality of care. Furthermore, health coverage plans operate in the interest of a group, not in the best interest of individual patients. Consequently, health insurers can increase profits by reducing the level of service and denying medical procedures that physicians would normally perform based on professional judgment. In the absence of competition among insurers, patients are more likely to pay for these procedures out-of-pocket or forego them entirely. Ultimately, the creation of monopsony power from a merger can adversely impact both the quantity and quality of health care.

Finally, the evidence from mergers throughout the U.S. strongly suggests that the creation of buyer power from health insurance consolidation has not benefited competition or consumers.[29] Although compensation to providers has been reduced, health insurance premiums have continued to increase rapidly. Moreover, evidence from other mergers suggests that insurers do not pass savings on from these mergers on to consumers. Rather, insurance premiums increase along with insurance company profits. As Professor Lawton Burns has observed in Congressional testimony:

[T]he recent historical experience with mergers of managed care plans and other types of enterprises does not reveal any long-term efficiencies.

[E]ven in the presence of [efforts to achieve cost-savings] and defined post-integration strategies, scale economies and merger efficiencies are difficult to achieve. The econometric literature shows that scale economies in HMO health plans are reached at roughly 100,000 enrollees. * * * Moreover, the provision of health insurance (e.g., front-office and back-office functions) is a labor-intensive rather than capital-intensive industry. As a result, there are minimal economies to reap as scale increases. * * * Finally, there is little econometric evidence for economies of scope in these health plans—e.g., serving both the commercial and Medicare populations. Serving these different patient populations require different types of infrastructure. Hence, few efficiencies may be reaped from serving large and diverse client populations. Indeed, really large firms may suffer from diseconomies of scale.[30]

Concerns about the merger's impact in the physician market were recognized by the Nevada Attorney General in the companion enforcement action brought in federal court in Nevada. The Nevada Attorney General, although filing a similar complaint, secured some relief to address physician reimbursement issues. The Department's failure to address these concerns demonstrates the inadequacy of its enforcement action.

In sum, the merger poses significant risks of harm in the market for the purchase of physician services and will lead to a diminution of the quality of healthcare in Clark County's underserved healthcare market. The DOJ should have secured relief that would have prevented this harm in the physician services market. In any case, the DOJ should provide an extensive statement on its reasons not to bring an enforcement action in this market, including whether the relevant market includes governmental payors.[31]

V. The DOJ Has Arbitrarily Departed From its Past Antitrust Enforcement Policies

As discussed earlier, the DOJ has brought enforcement actions against insurance mergers which threatened harm to the market for the purchase of physician services. In these cases, the DOJ adopted the position that antitrust should be concerned with monopsony

[23] Dranove Aff. at 6–7

[24] Francis H. Miller, Vertical Restraints and Powerful Health Insurers: Exclusionary Conduct Masquerading as Managed Care?, 51 Law & Contemp. Probs. 195, 222 (1998).

[25] 2A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law § 575, at 363–64 (2002).

[26] R. Hewitt Pate, Asst. Att'y Gen., Antitrust Div., U.S. Dept. of Justice, Statement Before the Senate Committee on the Judiciary Concerning Antitrust Enforcement in the Agricultural Marketplace, at 4 (Oct. 20, 2003), available at *http://www.usdoj.gov/atr/public/testimony/201430.pdf*.

[27] Mark V. Pauly, Competition in Health Insurance Markets, 51 Law & Contemp. Probs. 237 (1998).

[28] Peter J. Hammer and William M. Sage, Monopsony as an Agency and Regulatory Problem in Health Care, 71 antitrust L.J. 949 (2004).

[29] See testimony from: Examining Competition in Group Health Care, Hearing before the Senate Judiciary Committee, 109th Cong. (Sept. 6, 2006), and Health Insurer Consolidation—The Impact on Small Business, Hearing before the House Small Business Committee, 110th Cong. (Oct. 25, 2007).

[30] Testimony of Professor Lawton R. Burns re. the Highmark/Independence Blue Cross Merger, before the Senate Judiciary Committee (April 7, 2007).

[31] Providing clarity on the reasons not to bring an enforcement action in these markets is consistent with the Division's policy on ''Issuance of Public Statements Upon Closing of Investigations,'' available at*http://www.usdoj.goviatripublicimidelines/201888.htm* (factors that will lead to the issuance of a closing statement include ''whether the matter has received substantial publicity [and] the value to the public in receiving information regarding the reasons for non-enforcement (including public trust in the Department's enforcement, and the value of the analysis for other enforcers, businesses and consumers)''). DOJ has issued closing statements in other health insurance mergers. See DOJ Press Release No. 04–497 (statement closing investigation of UnitedHealth's acquisition of Oxford Health Plans), available at *http://www.usdoj.gov/atr/public/press_ release/2004/204674.htm.*

mergers harming suppliers without the necessity for evidence of harm to downstream consumers.

Accordingly in challenging Aetna's 1999 acquisition of Prudential and United's 2006 acquisition of PacifiCare, the DOJ addressed the harm to health care providers from the exercise of monopsony power. Both of these mergers were resolved with divestitures to facilitate the entry of new competitors to remedy the competitive concerns. In the Aetna/Prudential matter, the proposed merger would have increased Aetna's market share from 26% to 42% in Dallas, giving the merged entity a smaller share than would result from the merger here. Nevertheless, the DOJ concluded that the merger raised monopsony concerns by giving the merged firm the potential to unduly suppress physician reimbursement rates, resulting in a reduction of quantity or degradation of quality of medical services. The operative question from DOJ's perspective was could health care providers defeat an effort by the merged firm to reduce provider compensation by a significant amount, e.g. 5%. The question was answered in the negative for the same reasons explained by Professor Dranove in the instant case: physicians have limited ability to encourage patients to switch health plans, and physicians' time (unlike other commodities) cannot be stored, which means that physicians incur irrecoverable losses when patients are lost but not replaced. To exacerbate matters, contracts with physicians were negotiated on an individual basis, and were therefore susceptible to price discrimination by powerful buyers. Thus, DOJ concluded that Aetna had sufficient power to impose adverse contract terms on physicians, especially decreased physician reimbursement rates, which would ''likely lead to reduction in quantity or degradation in the quality of physicians' services.[32] As a remedy, the DOJ ordered Aetna to divest the business that would have given the merged entity monopsony power.

VI. The DOJ's Reversal in Its Enforcement Stance Comes Under Particularly Adverse Circumstances in Nevada

Merger analysis always focuses on the unique circumstances in every market. The Nevada healthcare market is particularly vulnerable, because of longstanding shortages of healthcare providers. Here are the simple facts:

- Nevada ranks 47th for access to care (based on the number of adults that should have visited a doctor but did not because of costs, and the number of uninsured);
- Nevada ranks 45th in access to physicians—approximately 25 percent below the nationwide median and has one of the lowest physician to population ratios;[33]
- Nevada ranks 51st in the country in quality of care (based on the number of adults receiving recommended screenings, diabetics receiving preventive care, Medicare patients that get enough time with a doctor);
- Nevada is last for immunization coverage for children under age 3—a fundamental role of primary care;
- Not surprisingly, based on the foregoing data, Nevada is 41st for mortality rates.

Assuming that Clark County's performance measures are similar to the rest of the state, allowing this merger into monopsony will for the reasons explained earlier, lead to a further reduction in quantity and degradation of quality of physician services. Thus, DOJ's refusal to adhere to its previous enforcement stance in cases of health insurer mergers into monopsony demand the attention of this court.

Turning to the market for the sale of commercial insurance where the parties control over 50% of the market in Clark County, Nevada, the record of health insurance coverage has been deplorable. Nevada has nearly half a million residents without health care coverage, almost 25 percent of the State. A high uninsured population not only presents health problems for those without coverage. When the uninsured do receive medical care, the costs are often shifted to the insured population; 2005 estimates indicate that health care treatment for uninsured persons in Nevada cost $397 million, $314 million of which was covered by higher premiums for those with insurance.[34] These factors too strongly suggest that the Court should be particularly judicious in evaluating the adequacy of the PFJ.

VII. No Relief in the Market for the Sale of Commercial Insurance

We believe that the DOJ also erred by not securing relief in the market for the sale of commercial insurance. Sierra and United were respectively the first and third largest sellers of commercial insurance products (including both .HMO and PPO products). The merger led to a combined share in the commercial insurance market of 56%. If the market was limited to HMO products, where United and Sierra were the two largest rivals the combined market share was 90%. In similar cases, the DOJ has required divestiture to resolve competitive concerns.

For example in United/PacifiCare, the DOJ defined a relevant product market as the sale of commercial health insurance to small group employers. This market consisted of employers with 2–50 employees. These employers were particularly susceptible to potential anticompetitive conduct because they lacked a sufficient employee population to self-insure and they lacked the multiple locations necessary to reduce risk through geographic diversity. In addition, the manner in which commercial health insurance was sold also distinguished the small and large group markets. Large employers were more likely than smaller employers to be able to successfully engage in extensive negotiations with United and PacifiCare.

We believe that both an HMO and small employer market may be adversely affected by the United-Sierra merger. Surveys demonstrate that consumers do not perceive HMOs and PPOs as substitute products, and consumers believe that they differ in terms of benefit, design, cost, and general approaches to treatment.[35] PPOs tend to provide more flexibility in selection of physicians and specialists and tend to be more expensive. In contrast, HMOs focus more on preventative medicine but limit treatment options and require referrals from a ''gatekeeper'' for many procedures. Moreover, small employers are less likely to have significant alternatives in response to a price increase by the merged firm. Small employers are unable to self-insure and have little power to negotiate better rates.

Again, as in the physician services market, the PFJ should be reopened to

[32] Aetna Complaint at paragraph 33.

[33] Nationally, there is a substantial and increasing shortage of physicians. *See e.g.* Health Resources and Services Administration (HRSA) *Physician Supply and Demand: Projections to 2020.* (Oct 2006) Projecting a shortfall of approximately 55,000 physicians in 2020) Merritt, J., J. Hawkins, et al. *Will the Last Physician in America Please Turn Off The Lights? A Look at America's Looming Doctor Shortage.* Irving, TX. Practice Support Resources, Inc. (2004) (Predicting a shortage of 90,000 to 200,000 physicians and that average wait times for medical specialties is likely to increase dramatically behond the current range of two to five weeks. This problem is far worse in Nevada.

[34] Paying a Premium: The Added Cost of Care for the Uninsured. Families USA (June 2005). Available at *http://www.familiesusa.org/assets/pdfs/Paying_a_Premium_rev_July_1373le.pdf.*

[35] *See United States* v. *Aetna,* Civil Action 3–99CV1398–H (N.D.Tex, 1999) (Revised Complaint Impact Statement).

secure relief in the commercial insurance market. In the alternative, the DOJ should issue a comprehensive statement of its reasons not to seek enforcement in this market.

VIII. Inadequacy of Remedies

Finally, the proposed remedies in the PFJ are inadequate in several respects. First, the restrictions that a dominant firm can impose on physicians are often critical to the acquirer of divested assets to effectively compete in the market. In this case, there are a variety of provisions that United can use that will deter the ability of the acquirer of the divested Medicare Advantage business to restore competition. For example, if Humana (the acquirer of United's Medicare Advantage business) were to attempt to attract greater physician coverage through attractive reimbursement rates, United could impose ''most favored nations'' provisions, which would prevent doctors from giving a more attractive rate to Humana. Similarly, United could utilize ''all products clauses'' which would require physicians to participate in United's Medicare Advantage program as a condition for participating in United's commercial program.[36] Professor Dranove explains how both of these provisions can be used in anti-competitive fashion.[37] The PFJ should have prevented the use of these provisions.[38]

Second, the DOJ requires solely the divestiture of the Medicare Advantage business rather than all of United's health insurance business in Clark County. This piecemeal approach faces a significant risk of failure. There is no evidence that a Medicare Advantage business can operate solely on its own without a commercial component. There are significant economies of scope and scale that exist when both commercial and Medicare Advantage businesses are combined. Moreover, the failure to divest an entire ongoing business is inconsistent with the DOJ's Merger Remedy Guidelines.[39]

The remedy is inadequate in several other respects. First, the DOJ recognizes the critical aspect of trademarks in being able to secure and keep an ongoing business. To elderly consumers the names ''United'' or ''Sierra'' are nowhere near as important or prominent as ''Secure Horizons,'' ''AARP'' or ''Senior Dimensions.'' In situations like this where trademarks are of particular importance to continue to secure customer loyalty, the antitrust agencies often prevent the merged party from using the trademark for a period of time. However, in this case the Justice Department imposed that obligation for only an extremely short period of time. Essentially within one to two years United can again reuse the Senior Dimensions (after March 31, 2010) or AARP (after March 31, 2009) trademark and lure customers to United's product.

We believe the remedy should be strengthened in the following fashion. First, the PFJ should require the divestiture of all of United's business and not just the Medicare Advantage business. Second, if the divestiture is limited to the Medicare Advantage business, the trademarks should be conveyed for at least five years. Third, United's use of all products clauses and most favored nations provisions should be permanently enjoined.

IX. United's Prior Acts of Broken Promises

In evaluating whether the remedies in the PFJ are adequate, it is critical to recognize United's past record of continual disregard of its regulatory obligations. No other health insurance company has been the subject of as many serious enforcement actions involving the violation of consumer protection and insurance regulations. This record of continual regulatory abuse raises a serious likelihood that United will fail to comply with any regulatory order. United has a long track record of disregarding its regulatory obligations and patient protection laws.[40]

In February 2008, California regulators imposed a potential penalty of $1.3 billion in fines against United for violating the law more than 130,000 times [41] after acquiring PacifiCare. Upon reviewing 1.1 million claims, the investigation found that after United acquired PacifiCare in 2005, United failed to pay claims in a timely manner and had over a 10% overall error rate in processing claims. United wrongfully denied claims for covered medical care, with regulators finding that 30% of reviewed HMO claims were denied incorrectly and 55% of certain claims were incorrectly denied as duplicate submissions when they were not in fact duplicate submissions. Regulators found that 29% of reviewed provider disputes were handled incorrectly, and that documents including medical records, had been lost by United. In addition, United lacked sufficient staffing to process claims in a timely manner and had failed to provide accurate lists of in-network providers to consumers. Finally, regulators in California found that United lacked efficient procedures to handle provider disputes.

Earlier this year, the New York Attorney General announced an investigation of United and other insurance companies for possible fraud. The New York Attorney General believes the insurance companies, including United, have used corrupted data from United-owned firm Ingenix to set unfair and unjustifiably low reimbursement rates for out of network physicians, resulting in higher out-of-pocket costs for consumers.[42]

In a landmark enforcement action in September 2007, Insurance Commissioners in 36 states assessed a $20 million fine against United Health for ongoing failures in processing claims and responding to consumer complaints.[43] This settlement establishes numerous claims processing payment requirements and makes provisions for substantial regulatory relief and additional fines during its term which does not expire until December 31, 2010.

Finally, other states have brought similar enforcement actions against United. In December 2006, the Nebraska Department of Insurance imposed its largest fine ever when it fined United $650,000 for failing to handle complaints, grievances and appeals in a timely fashion. In March 2006, the Arizona Department of Insurance fined United $364,750 (the largest fine in its history) for violating state law by denying services and claims, delaying payment to providers, and failing to keep proper records. In December 2005, the Texas Department of Insurance fined United $4 million for failing to pay claims promptly, lacking accurate claim data reports and not maintaining adequate complaint logs.

[36] All products clauses were prohibited in the consent order in United/Pacificare. *See United States* v. *UnitedHealth Group Inc.,* Case No. 05CV0436 (D.D.C. 2005) (Competitive Impact Statement at sec. III).

[37] Dranove Aff. at 8.

[38] There may be a suggestion that the relief in the Nevada consent decree may be sufficient to address these concerns. We do not agree with that view. The Nevada decree only prohibits these provisions for a short time—2 years. That period is inconsistent with the DOJ remedy in United/PacifiCare, which banned these provisions for the life of the Judgment.

[39] *See Antitrust Division Policy Guide to Merger Remedies,* U.S. Dept. of Justice, Antitrust Division at sec. III, C., (Oct. 2004).

[40] See American Medical Association letter to Nevada Commissioner of Insurance, Alice A. Molasky-Arman (June 5, 2007) concerning the history of United in failing to comply with state regulations (appended herein as Attachment B).

[41] Girion, Lisa, *Health Plan Faces Fines of $1.33 Billion*, Los Angeles Times, January 29, 2008.

[42] *Cuomo expands probe of health insurers.* Modern Healthcare Daily Dose. March 6, 2008.

[43] Allen, Marshal. *36 States Join to Fine UnitedHealth, Las Vegas Sun*, September 13, 2007.

We believe that these violations raise serious concerns about United's likely compliance with the provisions of the PFJ and highlight the need to strengthen the PFJ provisions. We suggest that the PFJ be modified to immediately impose the use of a monitor trustee to ensure compliance with the order.

X. Conclusion

After an 11-month investigation of a merger posing an unprecedented level of concentration in perhaps the most vulnerable healthcare market in the United States, the DOJ chose a modest remedy on a single line of business. That remedy is inadequate to resolve the concerns in the Medicare Advantage market and is inconsistent with the DOJ's Merger Remedy Guidelines. But more important, the FJ fails to address the significant loss of competition in both the purchase of physician services and sale of commercial insurance markets. Although the State of Nevada attempted to supplement the modest DOJ action, both actions permit a merger that poses a significant threat of causing substantial harm to consumers.

Thus, we believe the PFJ should be rejected. If the court, however, accepts the FJ, we strongly urge it to treat the PFJ as an interim remedy and expressly leave open the possibility of supplementing the PFJ with additional remedies to address these competitive concerns.[44]

Dated: May 15 2008.

Respectfully Submitted,
David A. Balto,
Attorney at Law,
2600 Virginia Ave., NW.,
Suite 1111,
Washington, DC 20037.

Attachment A

In the matter of: United States of America, Plaintiff v. UnitedHealth Group Incorporated and Sierra Health Services, Inc.; Defendants.

[Civil No. 1:08-cv-00322]

Judge: Ellen S. Huvelle.

Filed: 2/25/2008.

Affidavit of Professor David Dranove

I. Qualifications

I am the Walter McNerney Distinguished Professor of Health Industry Management at the Kellogg School of Management, as well as the Director of the Center for Health Industry Market Economics and the Director of *Health at Kellogg.* I have studied health care competition for over 20 years and have published numerous books and peer reviewed papers on the topic. My vita is attached.

I have also studied the Nevada health care market place, paying particular attention to physician markets in Clark County. This includes examining secondary data and supervising a physician survey. I am submitting this affidavit because I am concerned about the potential anticompetitive impact of the merger of UnitedHealth Group and Sierra Health Services, particularly the impact on the market for physician services.

II. Background [1]

The proposed merger between UnitedHealth Group and Sierra Health Services would create the largest private health insurer in Nevada. The Antitrust Division of the U.S. Department of Justice (DOJ) has reviewed this merger and filed a Complaint, Competitive Impact Statement, and Proposed Consent Order that narrowly focus on conduct and a remedy in the output market for Medicare Managed Care insurance. Specifically, UnitedHealth will be required to divest its Medicare Managed Care offerings as a condition for DoJ approval.

I have extensively researched health care competition, including competition among insurers. I have also studied the Nevada healthcare marketplace, including conducting interviews and a survey of Nevada physicians that I describe below. In my opinion, the DoJ focus on the Medicare Managed Care market is too narrow. In particular, the proposed remedy is inadequate because it fails to address the potential for the United/Sierra merger to create monopsony power in the market for the purchase of physician services.[2] It also does not address the potential for a dominant insurer to limit competition by such arrangements such as most favored nation contracts and bundling of contracts.

In the remainder of this affidavit, I explain why I believe the United/Sierra merger raises concerns about monopsony power in the market for purchasing physician services and also why it poses a substantial threat of anticompetitive behavior in output markets. With regards to the issue of monopsony in particular, I am concerned that the DOJ did not apply the proper economic analysis. I discuss monopsony in detail in sections III-VI of this affidavit. Section VII presents a shorter discussion of other issues. My main conclusion is that the United/Sierra merger may pose a substantial risk of harm in the market for the purchase of physician services that would adversely affect both healthcare providers and consumers, and that this risk was apparently underestimated by the DOJ.

III. Theory of Monopsony Power

Market Definition

In order to determine whether a merger poses a risk of the exercise of market power, or in this case, monopsony power it is essential to first define the market in which competition takes place. Markets are defined in both product and geographic dimensions. Competition between United and Sierra takes place in both input and output markets; I am focusing on input markets.

Market definition requires defining both a product market and geographic market. I will first consider the product market. Insurers purchase many inputs, including physician services. There are no adequate substitutes for physician services, due both to training and licensing laws. Moreover physicians are confined to supplying services within their training and licensures and cannot do something else in response to a decrease in compensation. Thus, the purchase of physician services represents a relevant product market.[3]

I believe that a relevant geographic market consists of an area no larger than the Las Vegas metropolitan area, which can be approximated by Clark County. This is a relevant geographic market from an input market perspective because physicians have limited alternatives in responding to a decrease in compensation. Physicians could not, for example travel to Los Angeles for additional business.[4] At the same time, insurers offering provider networks to Las Vegas area employers and employees could not expect to do

[44] See remarks of former Federal Trade Commission Chairman Robert Pitofsky, *A Slightly Different Approach to Antitrust Enforcement* before the Antitrust Section of the American Bar Association, Chicago Illinois (Aug. 7, 1995). Available at *http://www.ftc.gov/speeches/pitofsky/pitaba.shtm.*

[1] The American Medical Association paid for the time I spent researching the Nevada market and preparing this affidavit.

[2] Merger analysis focuses on the potential exercise of market power. ''Monopsony power'' is the power to decrease prices paid to producers or service providers who have little opportunity to sell other than to the monopsonist.

[3] There may well be even smaller markets within the physician services market, such as markets for specific specialties.

[4] Moreover, from the output market perspective the market is limited to Clark County. Insurers must market their provider networks to employers, who in turn make the network available to their employees. Most firms draw their workers from local areas, such as metropolitan areas. For example, it would be impractical for a Las Vegas casino to offer its employees a physician network that relied on physicians outside of Clark County.

business if their networks excluded Clark County providers. Thus, I believe it is indisputable that physician services in Clark County comprise a relevant market for antitrust analysis.

It Is Appropriate To Exclude Medicare and Medicaid

Competitive concerns arise whenever a firm, through merger, eliminates an important rival and gains the ability to influence prices. This is why market share calculations are so important to assessing mergers.

A critical issue in determining the likely effect of a medical insurer merger on the market for physician services may be whether to center the analysis on the commercial market share affected by the merger and to exclude Medicare and Medicaid, which are typically two of the largest purchasers in any medical market. The DoJ does not discuss potential monopsony power in the input market that I have defined, perhaps because it included Medicare and Medicaid beneficiaries in its calculation of buyer side market shares, and as a result the market shares of United and Sierra were not large enough to rise to the level of monopsony. But careful consideration suggests that the market for measuring monopsony power does not include Medicare and Medicaid.

A useful place to start thinking about this problem is to consider the more familiar problem of defining output markets. Suppose there are four firms—A, B, C, and D—equally dividing an output market. Suppose that firm A raises price by, say, $2 per unit. In the absence of collusive behavior, this effort is likely to fail, because consumers who are unhappy about the price increase will purchase the product from B, C, or D. This helps explain why antitrust analysts are rarely concerned about the potential exploitation of market power when there are many sellers in a market.

Now consider the same market with the same four sellers, only this time B, C, and D are capacity constrained. If A raises its prices, its consumers would either accept the increase or do without the product. They would not be able to take their business elsewhere. This gives seller A effective monopoly power over its customers. Thus, it is the ability of consumers to *redirect their business away from a high price seller,* and not the number of sellers *per se,* that limits a seller's ability to increase its prices.

The same intuition applies to monopsony. Suppose there are four purchasers of an input, again labeled A, B, C, and D. If purchaser A attempts to reduce the wage it pays for the input by $2 per unit, suppliers of the input would offer their services to purchasers B, C, and D. Thus, A's effort will fail. But if purchasers B, C, and D are constrained in the amount of labor inputs they can use in production, then sellers *will not be able to redirect their output* to these purchasers.[5] This gives purchaser A effective monopsony power over its suppliers.

With this intuition in hand, consider the market for physician services. Physicians who agree to participate in the network of insurer A accept a discounted fee from A in exchange for an expectation of higher volume. Physicians who do not agree to participate may still treat insurer A's enrollees as ''out of network'' patients, often requiring those patients to pay higher fees.

Suppose A reduces physician fees. As noted by the DoJ in their complaint against the merger between United and PacifiCare,[6] the ability of A to sustain this fee reduction ''depends on the physician's ability to terminate (or credibly threaten to terminate) the relationship. A physician's ability to terminate a relationship with a commercial health insurer depends on his or her *ability to replace the amount of business lost from the termination* (emphasis added), and the time it would take to do so. Failing to replace lost business expeditiously is costly.'' [7]

In determining the potential exercise of monopsony power, I assume the DoJ considered the options available to physicians. Physicians might refuse to contract with A. Insurer A's patients would then have to go out-of-network or seek a different insurer who has kept a broad network. (This is analogous to the case where the would-be monopsonist lowers its wages, and suppliers offer their services elsewhere.) Physicians might be proactive, joining rival networks and encouraging patients (and their employers) to switch plans. As a result, insurer A might end up with fewer enrollees. In this way, the presence of rival purchasers is essential if physicians are to have a ''credible'' ability to terminate their relationship with insurer A.

Physicians cannot increase volume or revenue by persuading their patients to sign up for Medicare, however, because enrollment in these programs is limited to the elderly and disabled.[8] Nor can physicians collectively treat more Medicare patients, because there are a limited number of patients and there is no means to increase the volume of patients. Thus, insurer A cannot lose physician business to Medicare; Medicare's business is fixed. Thus, from the perspective of physicians, the Medicare population is fixed. An analogous argument applies to Medicaid.

Even if physicians could collectively increase their Medicare and Medicaid workloads, this would not be an attractive alternative because Medicare, and, especially Medicaid, typically pay significantly lower rates than do private insurers. Medicaid rates are so much lower than most private insurer rates that few physicians would consider dropping insurer A in favor of Medicaid business even if insurer A lowered its rates appreciably.

The above argument demonstrates that when defining a relevant market for contracting for physician services, and computing market shares in that market, it is appropriate to exclude Medicare and Medicaid. Medicare and Medicaid do not represent viable alternatives for physicians who face lower fees from a monopsonist insurer. Because Medicare and Medicaid are large purchasers of physician services, excluding them from market share calculations will profoundly change inferences about market shares and monopsony power.

IV. Evidence on Monopsony Power

Physician Survey and Interviews

In my investigation I conducted physician telephone interviews in which I asked them about the competitive environment and how they might respond to the United/Sierra merger. Based on these interviews, I developed and oversaw a survey of physicians in Clark County. We sent surveys via e-mail, fax, and mail to the administrators of all 122 medical group practices identified in Clark County using the Universe File of the Medical Group Practice Association and to a random sample of 333 office-based physicians in the County, drawn from the American Medical Association Masterfile and oversampling primary care physicians and obstetrician-gynecologists. Twenty-four medical group administrators responded (for a response rate of 22.9% after adjustment for invalid and duplicate records). Seventy-three physicians responded (for an adjusted response rate of 27.5%). Additional details of the survey are

[5] Workers might offer their services to B. C, and D, but if these firms accept, they would have to lay off other workers, who in turn would face the same tradeoff as the new hires—work for A or stop working.

[6] *United States* v. *UnitedHealth Group Inc.,* Case No. 1:05CV02436 (D.D.C. Dec. 20, 2005), available at *http://www.usdoj.gov/atr/cases/f213800/213815.htm.*

[7] Complaint at Paragraph 36.

[8] The exception is Medicare managed care, as recognized by the DoJ consent order.

included as an appendix to this affidavit.[9]

Survey Findings Pertaining to Monopsony Power

A purchaser has monopsony power if it faces ''upward sloping supply.'' That is, the firm is able to reduce the price it pays for inputs without driving all of its input suppliers to other purchasers. One way to assess the potential presence of monopsony power is to determine whether suppliers have viable alternatives in the event they could not sell to the potential monopsonist. If a purchaser had monopsony power, then suppliers would respond in a variety of ways; some would sell to other purchasers, some would do nothing different, and some might even shut down operations. It is this range of responses—the varying degrees of leverage that a purchaser possesses over its suppliers—that characterizes upward sloping supply.

During my telephone interviews, I asked physicians how they would respond to the Sierra/United merger and a potential reduction in payments. Physicians offered a range of responses including closing their practice to doing nothing. To assess this issue more systematically, the survey included the following question: ''*What, if anything, would your practice do if United and Sierra merged and you did not continue to have a contract with the merged health plan?*''

Here are excerpts from a sampling of responses:

I'll go to California
Close practice
Leave town
I would consider relocating to another state or join the VA
This would hurt the practice tremendously. Actually I don't know what I'll do.
Nothing at present
Get on other contracts that will pay higher rates
Continue to service other health plans
Make do with remaining plans
We would be out-of-network provider and try to increase the other plans available
'Discourage patients from getting United/Sierra health insurance

The range of responses confirms what my telephone interviews had suggested, namely that some physicians have a viable alternative to United/Sierra but that many others would be harmed by losing the United/Sierra contract. This suggests that United/Sierra would have varying degrees of leverage over physicians, which is consistent with the ability to exercise monopsony power.

These data suggest that the United/Sierra merger may be creating substantial monopsony power within Clark County. It was incumbent upon the DoJ to explore this issue more thoroughly. Their complaint and the proposed order suggest that they failed to do so.

Market Concentration

In determining the competitive effects of any acquisition, it is often important to measure the level of concentration in the market. Unfortunately there is no significant public information available to compute market shares in the market for the purchase of physician services by commercial health insurers. One useful proxy would be the output shares of commercial health insurers. While the Bureau of Health Planning and Statistics of the Nevada State Health Division Department of Health and Human Services (henceforth, the ''Bureau'') collects data on HMO enrollments by plan and county, its data on PPO enrollments is incomplete.

The consulting firm Interstudy offers an alternative source of information about HMO and PPO market shares through their Managed Market MSA Surveyor and Managed Market State Surveyor databases. The American Medical Association has used these data to produce a report entitled ''*Competition in Health Insurance: A Comprehensive Study of U.S. Markets.*'' Based on the 2007 update of this report, I determined that the market shares for Sierra and United in the Las Vegas metropolitan area (which closely approximates Clark County) were 38% and 18% respectively. The combined market share is 56%. This combined share, as well as the increase in share, raise substantial concerns about monopsony power that the DoJ does not appear to have addressed.

V. Monopsony Power Can Harm Healthcare Consumers

Monopsony power can harm healthcare consumers in several ways. Part and parcel with a reduction in the compensation of physicians will be a reduction in the number of physicians who participate in the monopsonist's network. (This is the natural consequence of a monopsonist moving down its upward sloping supply curve.)[10] The patients who previously utilized the services of physicians who are no longer in the network must now either (a) select another, less preferred physician within the network, or (b) see their prior physician out-of-network and consequently pay higher out-of-network fees. Either way, these patients are worse off than before the exercise of monopsony power.

Even the patients of physicians who remain in the United/Sierra network may be worse off, because the reduction in the fees paid to these physicians may cause them to reduce the quantity and/or quality of services they provide. Physicians who receive lower fees will be forced to do more with less. This may result in longer waiting times as physicians are forced to reduce staffing. Economics teaches that physicians are to be expected to reduce their output; again, this is a standard prediction associated with upward sloping supply. Another standard result from economic theory is that sellers who experience lower price-cost margins will have less incentive to maintain quality.[11] There is substantial evidence that this occurs in medicine.[12]

Responses to the aforementioned survey question ''*What, if anything, would your practice do if United and Sierra merged and you did not continue to have a contract with the merged health plan?*'' confirm these concerns about patient welfare. As mentioned previously, some physicians might close their practices. Here are some additional responses:

Downsize practice
See a lot less patients
All patients would have to be self-pay under merged health plan
Lay off staff and reduce number of physicians on staff
I would consider having a cash only office

Several telephone interviews offered similar responses. All of these responses would have harmful repercussions for patients.

VI. Why Competition in the Output Market Would Not Discipline United/Sierra

A firm might not exercise its monopsony power if doing so harms its consumers who, as a result, turn to

[9] The survey had several limitations. Due to the desire to maximize responses, the survey was kept deliberately short. This limited our ability to tailor survey questions to address specific economic issues. Despite the brevity of the survey, the response rate was too low to reach definitive conclusions. Even so, the findings were sufficiently suggestive that, in my opinion, the DoJ. should have investigated these issues more thoroughly.

[10] When supply is upward sloping, a seller with monopsony power profits by reducing the wages it pays, relative to the competitive wage. By doing so, fewer suppliers offer their goods and services, so that the monopsonist ends up reducing the quantity of output it produces.

[11] See Spence, M. ''Monopoly, Quality, and Regulation'' *Bell Journal of Economics* 6(2), 1975 and Dranove, D. and M. Satterthwaite, ''Monopolistic Competition When Price and Quality Are Imperfectly Observable'' *RAND Journal of Economics,* 23(4), 1992.'

[12] Dranove, D. *The Economic Evolution of American Healthcare* Princeton University Press, 2000, reviews this evidence.

alternatives in the output market. In other words, output market competition might discipline the would-be monopsonist. The nature of the provision of medical services works against such market discipline. Suppose that physicians in the United/Sierra network are forced to cut back services in response to fee cutbacks. One might think that this would devalue the United/Sierra products, leaving it at a disadvantage relative to the competition. In other words, if physician services are ''public goods,'' whose quality applies to all of their patients, then the harmful effects of reduced monopsonist fees are felt by all patients and the monopsonist suffers no competitive harm.

There is a public good element in many physician decisions. If physicians reduce their office hours, this is likely to affect access for all of their patients. (Physicians who contract with a monopsonist could not normally limit their availability to the monopsonist's patients only.) Similarly, if a physician cuts back on staff and/or equipment, or invests less in continuing education, all patients would suffer. Of course, if the physician exits the market altogether, all patients suffer. If quality is a public good, as I conjecture, then the monopsonist can internalize all the benefits of fee reductions while the harm is felt by patients enrolled by all insurers. Thus, market forces do not necessarily discipline the monopsonist whose aggressive pricing causes quality to suffer.

Concluding Comments About Quality

Unfortunately, the DoJ complaint and consent order are silent on the issue of quality. In both the qualitative interviews and the survey conducted under my supervision, I learned about some of the ways that fee cutbacks could harm quality. Some of the alternatives physicians mentioned included exiting the market, curtailing their hours, spending less time with patients, and cutting back on staffing. In light of these responses, there should have been greater analysis of the potential impact of the United/Sierra merger on the quality of physician.

VII. Contractual Provisions That Raise Competitive Concerns

The purpose of merger enforcement is to prevent the creation of market power or its exercise. In some cases, in order to prevent competitive harm from a proposed merger the antitrust agencies and the courts may impose some type of injunctive relief. In this case, I believe the DoJ should have sought to prohibit two types of arrangements: most favored nation provisions and all products clauses.

Most Favored Nation Provisions

In my experience, many large insurers exploit their size by demanding and receiving most favored nation status from providers. A most favored nation provision requires the provider to offer the dominant insurer the most favorable rate it offers to any other insurer. Both theory and empirical evidence suggest that most favored nation status harms consumers by discouraging providers from aggressively discounting to other insurers.[13] Most favored nation provisions may prevent other insurers from entering or expanding in the market through these favorable discounting arrangements. The DoJ complaint and the proposed consent order are silent on this issue. The DoJ should have required the combined United/Sierra to foreswear MFN as a condition for approving the deal.

Bundling and All Products Clauses

It is also my experience that large insurers often require providers to abide by ''all products clauses'' whereby a provider who wishes to be a preferred provider for one of the insurer's products must agree to contract for all of that insurer's products. I am particularly concerned about the ability of a large insurer to bundle products in different markets. In particular, I believe that the combined United/Sierra will have monopsony power in the market for securing physician services for privately insured patients. It may now use that market power to bundle together contracting in the Medicare Advantage and private insurance markets. Such bundling would not offer any obvious promise of efficiencies and should be viewed with skepticism by anyone promoting market efficiency.

It is not obvious from the DoJ complaint and consent order whether these issues were investigated or how they were resolved. The DoJ should have explored these issues and if they believed there was potential for such bundling, the combined United/Sierra should have been required to allow physicians to contract separately for private insurance and the Medicare Advantage program.

May 13, 2008.

David Dranove,

Walter McNerney Distinguished Professor of Health Industry Management,
Northwest University.

[13] For example, see Scott Morton, F. ''The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules'' RAND Journal of Economics, 28(2), 1997 for an exposition of the theory and evidence from pharmaceutical pricing. The theory is broadly applicable to other markets including physician services.

Appendix: Survey Methods

Setup Procedures

All documents were verified by project client. Documents included the cover letter and survey instrument with a version each for the medical group sample and one for the physician practice sample.

All materials included the logos and respective signatures from: AMA, the county medical society, and the state medical society of Nevada.

The project client provided the sample database of medical groups and physician practices, including the name and phone number of a contact.

PRS provide the fax number and address for mailings in the phone calls, as appropriate.

Mailing Procedures Medical Group Sample

On February 12, 2008 Population Research Systems (PRS) mailed the survey to the medical groups, with a cover letter and business-reply envelope, to the 122 medical group administrators in the Clark County, NV medical group file. The outgoing envelope was addressed to the name of the person or the administrator, when available, otherwise the term ''Practice Administrator'' was included, for example: Ms. Jean Smith or Practice Administrator, Desert Medical Group, 1234 Pine Hill Drive, Las Vegas, 11111.

About 9–10 days after the initial mailing, PRS faxed another survey and cover letter, to all non-respondents from among the 122 group administrators.

Another 5 days later, the sample with non-responders, invalid or missing fax numbers was returned to the project client, who conducted a round of reminder phone calls and updated all invalid fax numbers. Contacted medical groups who requested another fax received one from PRS within 24 hours of that information being provided by the project client. PRS also sent another fax to all invalid and missing fax numbers.

About 6 days after the reminder call, PRS sent another round of faxes to all non-responders.

Another 10 days later, PRS initiated another round of faxes to all non-responders, followed immediately by a second round of reminder calls conducted by the telephone staff of PRS. PRS attempted every record until a respondent or answering machine was reached, and PRS telephone interviewers left scripted messages on answering machines (see below).

Telephone Reminder Script

Hi, my name is ___, and I am calling on behalf of the AMA. Yesterday, we sent you a fax with a very brief survey about the United/Sierra merger in Clark County, and we are very interested in your opinion. Please take a few minutes to complete the survey and fax it back to the number shown on the cover letter. We will keep your responses confidential.

If Not Received Fax:

Can you confirm your fax number for me so we can send you another fax?

We appreciate your participation. Thank you.

Response Rate

This effort resulted in a total of 24 completed surveys, out of a sample of 102 records. Of those 102 records, 7 records were invalid (group did not exist, was closed, wrong address/name) and 101 records were duplicates within the sample, resulting in 86 valid records. Out of those 86 valid records, 24 completes constitute a corrected response rate of 28.2%.

Count of IDs	
Status	Total
Complete	24
Invalid record	7
No response	61
Duplicate record	10
Grand Total	1021

Mailing Procedures Individual Physician Sample

On February 12, 2008 PRS e-mailed the cover letter and survey embedded in the body of the e-mail message to 353 physicians identified by the project client. PRS inserted the medical society logos into the email itself, as well as the signatures, similar to the Medical Group survey.

About 3 days after the initial e-mail, PRS faxed a reminder survey to all physicians who had not responded at that point. The cover letter for the fax was slightly different from the e-mail cover letter to reflect the change of modus.

Approximately 8 days later, the sample with non-responders, invalid or missing fax numbers was returned to the project client, who conducted a round of reminder phone calls and updated all invalid fax numbers. Contacted medical groups who requested another fax received one from PRS within 24 hours of that information being provided by the project client. PRS also sent another fax to all invalid and missing fax numbers.

About 7 days after the reminder call, PRS sent another round of faxes to all non-responders.

Another 6 days later, PRS initiated another round of faxes to all non-responders, followed immediately by a second round of reminder calls conducted by the telephone staff of PRS. PRS attempted every record until a respondent or answering machine was reached, and PRS telephone interviewers left scripted messages on answering machines (see script above).

During this process, PRS noted that 13 records of the original sample were duplicates (duplicate e-mail, address and fax number, and those records were replaced with another 13 records, resulting in a final total of 353 records.

Response Rate

This effort resulted in a total of 73 completed surveys, out of a sample of 353 records. Of those 353 records, 55 records were invalid (group did not exist, was closed, wrong address/name) and 13 records were duplicates within the sample, resulting in 285 valid records. Out of those 285 valid records, 73 completes constitute a corrected response rate of 25.6%.

Count of IDs	
Status	Total
Complete	73
Invalid record	55
(blank)	212
Duplicate record	13
Grand Total	353

Attachment B

June 5, 2007.

Honorable Alice A. Molasky-Arman
Nevada Commissioner of Insurance
Division of Insurance-Legal Section
788 Fairview Drive, Suite 300
Carson City, NV 89701–5491

Re: UnitedHealth Group Acquisition of Sierra Health Systems

Dear Commissioner Molasky-Arman:

The AMA is writing to express its strong opposition to the proposed acquisition of Sierra Health Systems (Sierra) by UnitedHealth Group (United). The AMA has urged the United States Department of Justice to block the merger because of the impact in Nevada. The impact in the state of Nevada is unlike the impact in any market of any previous health insurer merger. Our testimony will focus on the anti-competitive effect this merger will have on Nevada insurance markets, a negative effect that will be compounded by questionable business practices engaged in by United in other markets. We also strongly support the position of the Nevada State Medical Association.

It is clear that United's goal in pursuing this merger is to dominate the Nevada insurance market, in particular Las Vegas. The numbers are truly staggering, as shown in the attached chart. For the past five years, the AMA has conducted the most in-depth study of commercial health insurance markets (by actual reported enrollment) in the country. This study, *Competition in Health Insurance: A Comprehensive Study of U.S. Markets,* is based on the most current and credible data available and includes both HMO and PPO products. The AMA is in the process of finalizing our most recent edition, based on 2004 data. The findings for Nevada strongly suggest that this merger undermines competition in Nevada and in Las Vegas especially.

The AMA analysis of InterStudy and HealthLeaders data shows the following:

- At the state level, in the combined HMO/PPO market, United would have a market share of 43% after the merger, compared to its current market share of 14%. In the HMO market, United would have a 78% market share after the merger, compared to its current 11 % market share.

In the Las Vegas-Paradise metropolitan statistical area (MSA), in the combined HMO/PPO market, United would have a market share of 56% after the merger, compared to its current market share of 18%. United would have a market share of 95% after the merger, compared to its current market share of 13% in the HMO market.

These market shares should be considered in the context of the financial aspects of United's operations. At a time when premiums continue to escalate, United is posting high profit margins. Since 2002, United has posted year-end earning increases of between 27% and 53%. For 2006 its net earnings increased 27%. United has also awarded its senior executives mind-boggling compensation packages over this same time period. United is currently in the midst of several ongoing investigations and shareholder lawsuits over illegally backdating senior executives' stock options to increase their already extravagant compensation.

The Threat of Market Dominance

The AMA has long been concerned that ongoing consolidation of health insurance markets will ultimately lead to a market dominated by one or two health insurers that places profits over patients. The ascendancy of a dominant health insurer jeopardizes patient care in two important ways. First, without competition to help ensure that patient and employer choice counterbalance profit motives, the for-profit health

insurer's drive to maximize profits will inevitably compel it to place profits over patients.

Second, physicians have a professional, legal, and ethical responsibility to advocate on their patient's behalf. In the presence of health plan dominance the physician's role as patient advocate becomes even more critical. However, that role is being systematically undermined as dominate insurers are able to impose take-it or leave-it contracts that include provision that directly impact patient care, such the determination of what is ''medically necessary care.'' A physician who engages in aggressive patient advocacy risks exclusion from the dominant health plan's network and faces the realistic possibility that his/her practice will no longer be financially viable. In the presence of these dynamics, only state oversight and intervention can prevent deterioration of the patient-physician relationship, foster physician advocacy, and make patient choice a reality.

United's Failure to Comply With State Regulations

United's conduct shows a dismissive attitude towards its state regulatory obligations. It has been fined by a number of states for failing to comply with state law since 2001. Moreover, in some of those states, United has been fined more than once for the same conduct. United has the unenviable position of having had the largest fines ever levied against a health insurer in several states.

Specific examples include:

Arizona: In March 2006, the Arizona DOI fined United for the second time for violations of a number of state laws. These include state prompt payment laws, and state laws on member's rights to appeal denials of care. United was fined $364,750, the largest fine in Arizona's history. This was the second fine levied against United for similar violations. The first was in 2003. In the 2006 case, the director of the Arizona DOI stated that, ''I will not tolerate knowing violations of consent orders.''

- *Nebraska:* In December 2006, the Nebraska DOI filed a complaint which stated that United violated 18 state laws over 800 times. United delayed decisions, made incorrect decisions about coverage, and had an inadequate network of emergency services in rural areas. A settlement was reached in May 2007. It includes a $650,000 fine, the largest ever levied by the Nebraska DOI. The settlement also requires United to meet customer service standards and to give United's Nebraska staff the final decision on claims and grievances. This was the second time United has been fined for similar state law violations. The 2005 investigation resulted in United paying a $72,500 fine.
- *New York:* In 2006, the New York State Health Department took the unusual step of banning United from enrolling any new customers in its HMO plan because United continued to repeatedly defy state regulations. These include wrongly denying payment to providers and filing incomplete and inaccurate reports with the state. A state official noted that, ''we've had several years of findings, United doing corrective action plans, but then we go out again, and we have the same findings.''
- *Rhode Island:* In April 2007, UnitedHealthcare of New England was fined $67,500 for violating a state law intended to protect health-insurance coverage for small-business employees. United failed to provide documentation showing that it had complied with the law. In addition, according to documents released by the Health Insurance Commissioner's office, United overcharged members who were in poor health.
- *Texas:* Between 2001 and 2005, the Texas Department of insurance (TDI) has fined United three times for violating Texas prompt pay laws. The most recent fine, issued in December 2005, included a finding that United failed to report accurate and complete provider claims data for over 2 years. The 2005 fine totaled $4 million and United also agreed to pay restitution to physicians.
- *Missouri:* In *Schoedingerg* vs. *United,* a Missouri physician sued United for failing to comply with the state prompt payment law. In its finding of facts, the court found that the plaintiff had proven that United did not pay his claims within the time period set by Missouri law. Specifically, the 2006 opinion found that ''United's claims processing system was flawed in many ways, including denying, reducing and improperly processing claims on a regular basis. And despite innumerable requests, United was unwilling to remedy the underlying errors in its systems. United was consistently delinquent in paying claims.''

Ongoing State Investigations of United's Business Conduct

In the past several months, two states have announced investigations into United's business practices and whether they comply with state law. These investigations are specified below.

- *California:* The California Department of Insurance and the California Department of Managed Health Care (CDMHC) have announced an investigation into a range of United business practices. According to the California Medical Association (CMA), there is a liaison process between CMA and United. While United is generally responsive to the individual physician complaints, it is not responsive to fixing the underlying issues. This causes the objectionable practices to continue which must be battled one physician and one claim at a time. The regulators indicated that their objective is to bring United into compliance with state laws for the benefit of California patients.
  - *Note:* in May 2007, the CDMIIC found that United subsidiary PacifiCare engaged in ''dishonest and unfair'' conduct when it failed to disclose its planned termination of a provider network during open enrollment. The CDMHC ordered PacifiCare to continue to authorize and allow access to the network through November 2007.
- *New Jersey:* In April 2007, the New Jersey Department of Banking and Insurance ordered United to justify a lab referral protocol that has outraged physicians across the country. This policy, which was the outgrowth of a 10-year exclusive contract with Lab Corp, provides that if physicians refer to an out-of-network lab, they can be fined or dropped from the network. This is the first instance of a health plan threatening financial penalties for out-of-network referrals. The DOBI ordered United to ''appear and show cause why it should not be required to pay restitution or take other remedial measures.'' This is in regards to the effects of its proposed sanctions on physicians.

The AMA believes that United's conduct reflects a philosophy that it is more cost-effective to violate state law and possibly pay a fine than to assure compliance with laws designed to protect both patients and physicians. The AMA's first concern is that this unprecedented merger will create monopoly conditions in Nevada to the detriment of Nevada citizens. That being said, given the magnitude of this merger in Nevada and United's track record in other states, if this merger is allowed to go forward, it is incumbent on the Nevada Department of insurance to assure that United is held accountable for compliance with state laws.

If the AMA can be of further assistance, please do not hesitate to contact me. The AMA appreciates the opportunity to comment on this matter.

Sincerely,

Michael D. Maves, MD, MBA.
Attachment
cc: Larry Matheis, Executive Director, Nevada State Medical Association.

Attachment C

Testimony of David Balto On Behalf of the American Antitrust Institute and Consumer Federation of America Before the Nevada Commissioner of Insurance on the United Health Group Proposed Acquisition of Sierra Health Services [1] (July 27, 2007)

I. Introduction

The American Antitrust Institute (''AAI'') and Consumer Federation of America, (''consumer groups'') appreciate this opportunity to testify before the Commissioner of Insurance on United Health Group's (''United'') proposed acquisition of Sierra HealthServices, Inc. (''Sierra'').[2] As detailed in our testimony based on our preliminary review, we strongly believe that this acquisition will harm all Nevada health insurance consumers, particularly those in Clark County, through higher prices, less service, and lower quality. The level of concentration posed by this merger is simply unprecedented: it is greater than in any merger approved by the Antitrust Division of the U.S. Department of Justice (''DOJ'') and would give United clear monopoly power in Clark County.

In evaluating this merger under NRS 692C.210(1) the Commissioner of Insurance must consider several factors including: (1) whether ''the effect of the acquisition would be substantially to lessen competition in insurance in Nevada or tend to create a monopoly'' and (2) whether if approved the ''[a]cquisition would likely be harmful or prejudicial to the members of the public who purchase insurance.'' As we explain below, both of these factors counsel for denial of the application because the merger creates a dominant insurer, particularly in Clark County, with the ability to raise premiums, reduce service and quality and reduce compensation to providers. It will clearly harm purchasers of insurance who will pay more for service that provides lower quality care.

This unprecedented level of concentration raises important policy and health care concerns relevant to the factors evaluated in these Hearings. As Vermont Senator Patrick Leahy observed in Hearings before the Senate Judiciary Committee last year on health insurance consolidation:

> a concentrated market does reduce competition and puts control in the hands of only a few powerful players. Consumers—in this case patients—are ultimately the ones who suffer from this concentration. As consumers of health care services, we suffer in the form of higher prices and fewer choices.[3]

Creating a dominant insurance provider should be a profound concern in Nevada, a state plagued with shortages of nurses, doctors and other health care professionals.

This testimony, which is based solely on public information, provides our preliminary views that this merger would ''substantially to lessen competition in insurance in Nevada or tend to create and monopoly'' and ''would likely be harmful or prejudicial to the members of the public who purchase insurance.'' This paper also addresses the United-Sierra merger in the context of the numerous competitive imperfections and market failures unique to the HMO and health insurance industry and with respect to the specific challenges facing Nevada's health care due to a serious shortage of doctors and nurses.

II. Summary

The consumer groups urge the Commissioner to focus on the following issues:

- *Will the United-Sierra merger reduce competition for the provision of health insurance to employers and individuals seeking health coverage in Nevada?* Yes, Sierra is the largest HMO provider in Nevada and United is the only significant rival. The United-Sierra merger in Nevada would give United a 80% market share of all HMOs in Nevada and a 94% market share of the HMO market in Clark County. Although its market share is smaller than Sierra's, United has the potential for significant growth in Nevada since its acquisition of PacifiCare in 2005. Moreover, the next largest HMO rival in Clark County has only a 2% market share. The merger would adversely affect a wide range of buyers including small employers, governmental and union purchasers.
- *Will the United-Sierra merger reduce competition for the provision of services in the Medicare Advantage program?* Yes. Medicare is increasingly turning to a managed care model. Increasingly Medicare beneficiaries are signing up for the Medicare Advantage program which provides health care services to beneficiaries in a managed care model. The only current bidders for Medicare advantage in Nevada are United and Sierra. United is the largest Medicare Advantage program in the U.S. The merger would create a monopoly in the provision of services for Medicare Advantage program resulting in a lower level of care and prices.[4]
- *Could the United-Sierra merger increase the threat of monopsony power and reduce access to medical care and the quality of medical care in Nevada?* Yes, there is currently a significant and chronic shortage of health care providers including physicians and nurses in Nevada, an understaffed region where health professionals are forced to work overtime, double-shifts, weekends, and holidays. This merger will exacerbate those problems for health care providers dependent upon the merged firm. A combined United-Sierra can reduce compensation resulting in a diminution of service and quality of care. In the past the DOJ has brought enforcement actions because of concerns over monopsony power where the market share exceeded 30%, a level clearly exceeded by this acquisition. This merger may lead to a significant reduction in reimbursement for health care providers, leaning to lower service and quality of care.
- *Will other insurance companies readily enter the market (or expand) and fully restore the competition lost*

[1] I have practiced antitrust law for over 20 years, primarily in the federal antitrust enforcement agencies: the Antitrust Division of the Department of Justice and the Federal Trade Commission. At the FTC, I was attorney advisor to Chairman Robert Pitofsky and directed the Policy shop of the Bureau of Competition. Maria Patente, Washington College of Law (Class of 2008), provided extensive assistance in the preparation and research of the testimony.

[2] The American Antitrust Institute is an independent Washington-based non-profit education, research, and advocacy organization. Its mission is to increase the role of competition, assure that competition works in the interests of consumers, and challenge abuses of concentrated economic power in the American and world economy. For more information, please see *www.antitrustinstitute.org.* This working paper has been approved by the AAI Board of Directors. A list of contributors of $1,000 or more is available on request. The Consumer Federation of America (''CFA'') is the nation's largest consumer-advocacy group, composed of over 280 state and local affiliates representing consumer, senior citizen, low income, labor, farm, public power and cooperative organizations, with more than 50 million individual members. CFA represents consumer interests before federal and state regulatory and legislative agencies and participates in court proceedings. CFA has been particularly active on antitrust issues affecting health care.

[3] Statement of Senator Patrick Leahy, Hearing on ''Examining Competition in Group Health Care'' U.S. Senate Committee on the Judiciary (Sept. 6, 2006).

[4] A large number of the consumer complaints filed with the Commissioner about this merger raise concerns over the loss of competition in the Medicare Advantage market. Many of these complaints are from elderly beneficiaries who are particularly vulnerable to anticompetitive conduct. Over 30% of Nevada Medicare beneficiaries subscribe to Medicare Advantage, one of the highest enrollments of any state.

from the merger? No. In some cases it may be unnecessary to challenge a merger if other firms can readily enter a market to a sufficient degree to avert the anticompetitive effects of the merger. That is clearly not the case for this market. As the DOJ has recognized in other cases, barriers to entry in the HMO market are extremely high due to the extensive physician networks, technology networks, and specialized medical infrastructure that are essential to the industry. Moreover, Nevada already faces a serious shortage of both doctors and nurses, and attracting a sufficient number of personnel would pose a high barrier for a new entity interested in providing HMO plans in Nevada. There has been little historical entry into the Nevada HMO market, in spite of the growth of population. Moreover, with a dominant United-Sierra, it is highly unlikely a new entrant would undertake the risk of new entry.

• *Do the efficiencies from the United-Sierra outweigh the anticompetitive harms?* No. The parties have not proposed significant efficiencies from this consolidation. If there were any efficiencies they probably could be achieved through internal growth, considering the rapid population growth in Nevada. Moreover, efficiencies should only be included in the competition calculus if they will result in lower prices or better service to consumers. As a general matter, efficiencies from health coverage mergers have not been passed on to consumers. Health insurance mergers have generally led to increased subscriber premiums without expansion of medical benefits. There is little evidence if any that any efficiencies achieved in the United-PacifiCare merger have resulted in lower premiums or better service for United or former PacifiCare subscribers. Since the combined United-Sierra would have a dominant market share post-merger it is highly unlikely any savings would be passed on to consumers.

• *Would a divestiture or other structural relief be sufficient to alleviate the competitive problems raised by the merger?* No. The parties have not suggested that they would be willing to divest assets to solve the competitive concerns raised by the merger. Even if they did the Commissioner should be extremely skeptical of any proposed relief. In the past the DOJ has attempted to resolve competitive concerns over some mergers by requiring the divestiture of a certain number of contractual arrangements in order to spur new entry. These divestitures have been insufficient to cure the competitive problems posed by those mergers. A divestiture is even less likely to resolve the competitive concerns in this merger where the merged firm will clearly be the dominant insurer in the market.

• *Would consumers be better off if the Commissioner rejected the merger?* Yes. The antitrust question in evaluating any merger is what would happen ''but for'' this merger? What would happen to the merging parties, consumers, and providers? The answer in this case seems rather transparent. United and Sierra are both successful, financially sound, capable companies that would continue to grow and thrive. Through its acquisition of PacifiCare, United established an important beachhead in Nevada. But for this merger, United would continue to expand in Nevada and challenge Sierra's strong position in the market. That competition between United and Sierra would lead to lower premiums, greater innovation and better service. There is simply no reason why United can not achieve most of the benefits of this acquisition through internal growth.

The remainder of the testimony is set forward as follows. First, we make some observations about special considerations for health insurer mergers and suggest why regulators and enforcers can not rely on the theoretical assumptions of a competitive market. Then we focus on past enforcement actions and the principles of antitrust enforcement. We then explain how the merger will reduce competition in both the provision of certain health insurance products (impact on buyers) and health care providers (impact on sellers). Finally, we explain why other factors such as ease of entry or efficiencies will not prevent the anticompetitive effects of the merger.

III. Antitrust Merger Standards and Past Antitrust Enforcement Actions

The U.S. antitrust laws, like the Nevada insurance statute, provide that a merger may be illegal if it may ''tend substantially to lessen competition or to tend to create a monopoly.'' [5] The concern under the merger laws is that a merger may tend to reduce competition and lead to higher prices, lower service, less quality, or less innovation. Concerns over a reduction in quality, central to the delivery of health care services, is an important element of competition.[6] As the Supreme Court has observed, competition protects ''all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost.'' [7]

In order to determine the likely competitive effects of a merger the case law and the Merger Guidelines established by the Department of Justice and the Federal Trade Commission set forth a multi-step process.[8] The process begins by defining the ''line of commerce'' or relevant product market and the ''section of the country'' or relevant geographic market. A relevant market can include any group of products or services. Once a relevant market is defined, the level of concentration and market share is calculated to determine the likely competitive effects of the merger. In cases where there is an undue level of concentration in the relevant market (generally a market share over 30%) there is a prima facie case of illegality and a presumption of unlawfulness.[9] If there is a presumption of unlawfulness then the burden shifts to the defendants to rebut the prima facie case and

[5] Clayton Act, 15 U.S.C. § 18. There is no case law evaluating the competitive legality of mergers under NRS 692C.210(1), however the language of the statute is identical to the Clayton Act. Thus, it is appropriate to apply the standards of federal antitrust law. The Nevada antitrust statute is similar to the Clayton Act. It prohibits mergers that will ''result in the monopolization of trade or commerce * * * or would further any attempt to monopolize trade or commerce'' or ''substantially lessen competition or be in restraint of trade.'' NRS 598A.060(1)(f).

[6] Section 7 prohibits anticompetitive reductions in quality because it is equivalent to an increase in price—consumers pay the same (or greater) price for less. *Community Publishers, Inc.* v. *Donrey Corp.,* 892 F. Supp. 1146, 1153 n.8 (W.D. Ark. 1995), *aff'd sub nom. Community Publishers, Inc.* v. *DR Partners,* 139 F.3d 1180 (8th Cir. 1998); *Merger Guidelines,* § 0.1 (''Sellers with market power also may lessen competition on dimensions other than price, such as product quality, service, or innovation.''); *id.* § 1.11.

[7] *Nat'l Soc'y of Prof. Eng'rs* v. *United States,* 435 U.S. 679, 695 (1978).

[8] U.S. Dep't of Justice and Federal Trade Comm'n, *Horizontal Merger Guidelines* (1997) (hereinafter *''Merger Guidelines''*). The Nevada statute provides that in determining whether to approve a merger the Commissioner of Insurance ''shall consider the standards set forth in the Horizontal Merger Guidelines * * *'' NRS 692C.256(2).

[9] Concentration in merger cases is expressed in terms of market shares and a measure known as the Herfindahl Hirschman Index (''HHI''). The HHI is calculated by adding together the squares of the market share of individual competitors in the market. In a market with a single seller, the HHI is 10,000. The FTC/DOJ Merger Guidelines provide that an HHI below 1000 corresponds to an ''unconcentrated'' market; an HHI between 1000 and 1800 corresponds to a ''moderately concentrated'' market, and an HHI above 1800 corresponds to a ''highly concentrated'' market. The HHI is a screening tool used to assess whether a proposed merger will lead to anticompetitive consequences. Under the Guidelines different presumptions apply, depending on the extent of post-merger market concentration and the increase in HHI that will result from the merger. The greatest competitive concerns are raised where the post-merger HHI exceeds 1800. In such cases, it is ''presumed that mergers producing an increase in the HHI of more than 100 points are likely to create or enhance market power or facilitate its exercise.'' *Merger Guidelines,* § 1.51.

demonstrate that other market characteristics make the presumption of anticompetitive effects implausible. Two types of evidence are prominent in merger cases—if the defendants can offer evidence that entry is relatively easy, that may dispel the notion that the merger will lead to significant anticompetitive effects. Finally, if a merger will lead to substantial efficiencies, these may counteract those anticompetitive effects.

The two most instructive antitrust cases involving health insurance mergers are the DOJ's challenges to Aetna's 1999 acquisition of Prudential and United's 2006 acquisition of PacifiCare. Both of these mergers were resolved with divestitures to facilitate the entry of a new competitor to remedy the competitive concerns. Each case focused both on the harm to purchasers of HMO and other insurance services from the exercise of monopoly power and the harm to healthcare providers from the exercise of monopsony power.[10] In both the United-PacifiCare and the Aetna-Prudential mergers, the DOJ identified highly concentrated markets that were substantially likely to suffer harm to competition as a result of these mergers.

In 1999, the DOJ and the State of Texas settled charges that the merger between Aetna and Prudential in the State of Texas would harm competition. The DOJ focused on relevant markets of HMO products and physician services. Aetna and Prudential were head to head competitors in the HMO markets in Houston and Dallas. The proposed merger would have increased Aetna's market share from 44% to 63% in Houston and 26% to 42% in Dallas.[11]

Moreover, the merger raised monopsony concerns by giving the merged firm the potential to unduly suppress physician reimbursement rates in Houston and Dallas, resulting in a reduction of quantity or degradation of quality of medical services in the areas.[12] The operative question from DOJ's perspective was could health care providers defeat an effort by the merged firm to reduce provider compensation by a significant amount, e.g., 5%. The question was answered in the negative for several reasons: physicians have limited ability to encourage patients to switch health plans, and physicians' time (unlike other commodities) cannot be stored, which means that physicians incur irrecoverable losses when patients are lost but not replaced. To exacerbate matters, contracts with physicians were negotiated on an individual basis, and were therefore susceptible to price discrimination by powerful buyers. Thus, DOJ concluded that Aetna had sufficient power to impose adverse contract terms on physicians, especially decreased physician reimbursement rates, which would ''likely lead to a reduction in quantity or degradation in the quality of physicians' services.'' [13]

To resolve these competitive concerns the DOJ ordered Aetna to divest its entire interest in NYLCare-Gulf Coast and NYLCare-Southwest, its Houston and Dallas commercial HMO business. This consisted of 260,000 covered lives in Houston and 167,000 covered lives in Dallas.

In 2006, the DOJ investigated the merger between United and PacifiCare and focused on potential competitive concerns in relevant markets for commercial health insurance for small group employers in Tucson, Arizona and physician services in both Tucson and Boulder, Colorado.[14] Small group employers are employers with 2–50 employees. The merger would have combined the second and third largest providers of commercial health insurance in Tucson and increased United's market share from 16% to 33%.

The merger also raised concerns over the potential harm to competition in the purchase of physician services in both Tucson and Boulder. The DOJ explained that by combining United and PacifiCare ''the acquisition will give United the ability to unduly depress physician reimbursement rates in Tucson and Boulder, likely leading to a reduction in quantity or degradation in the quality of physician services.'' [15] In other words the DOJ found that a health plan's power over physicians to depress reimbursement rates can be harmful to patients—the ultimate consumers of health care. The market shares involved were relatively modest: in excess of 35% in Tucson and in excess of 30% in Boulder ''for a substantial number of physicians in those areas.''

In response to the potential harm to competition, the DOJ required United to divest contracts covering at least 54,517 members residing in Tucson, Arizona to yield a post-merger market share equal to its pre-merger market share. Furthermore, the DOJ required United to divest 6,066 members covered under its contract with the University of Colorado. This divesture constituted nearly half of PacifiCare's total commercial membership in Boulder.

The antitrust laws protect not only consumers but any group of buyers, potentially including a governmental buyer. Buyers of health insurance services have varying needs and ability to secure competitive rates. An example of this is a case filed by the City of New York challenging the merger between Group Health Incorporated (''GHI '') and the Health Insurance Plan of greater New York (''HIP'') in the fall of 2006.[16] There are numerous health insurance competitors, including HMOs and PPOs in the New York City market, but for the low cost product required by the City and affiliated entities the only rivals were GHI and HIP. The case alleged that the merger of GHI and HIP would create a monopoly in the New York metropolitan area market for low cost health insurance purchased by the City of New York and its employee unions together with the city's employees and retirees as well as 35 other employers with ties to the city and their employees and retirees such as the Housing Authority, the Metropolitan Museum of Art and universities (all of which participate in the New York City health benefits program). The case alleges that city employees and retirees and those individuals who participate in the health benefits program would be faced with increased costs for insurance and reduced service if the merger were consummated. Litigation in the case is ongoing, but it suggests the broad range of markets that can be adversely affected by a merger.

[10] Health insurers play dual roles as sellers of insurance services and buyers of health care services. In its first role, the health insurer's ''output'' consists of health benefit packages, and the output prices are paid for by customers in the form of subscriber premiums. In the role as the seller of health benefits, a dominant health insurer in a concentrated market could potentially act as a ''monopolist'' charging an above market price for health benefits. In its second role, the health insurer acts as a buyer, and the input consists of physician and other medical services. The insurer's input prices are the compensation it pays in the form of physician fees and fees for medical services. In this role, the health insurer may act as a ''monopsonist,'' reducing the level of services or quality of care by reducing compensation to providers. Health insurers are both buyers of medical services and sellers of insurance (to consumers), so insurance mergers can raise both monopsony and monopoly concerns.

[11] These market shares are substantially smaller than the market shareswhich would result from the United-Sierra merger in the HMO markets of Nevada and Clark County (80% in Nevada and 94% in Clark County).

[12] *United States* v. *Aetna,*, Revised Competitive Impact Statement, Civil Action 3–99CV1398–H.

[13] *Id.*

[14] *United States* v. *UnitedHealth Group Inc.,* Case No. 1:05CV02436 (D.C.C. Dec. 20, 2005), *available at* http://www.usdoj.gov/atr/cases/f213800/213815.htm.

[15] *United States* v. *UnitedHealth Group,* Competition Impact Statement at 8, available at http://www.usdoj.gov/atr/cases/f215000/215034.htm.

[16] *City of New York* v. *Group Health Inc., et al.,* (S.D.N.Y. 2006).

IV. Special Information Concerns for Health Insurance Mergers

In determining the competitive effect of a merger the crucial issue is the impact on the consumer, the ultimate beneficiary of the insurance system. The questions to be examined include will consumers have to pay more for insurance in higher premiums or deductibles, will they suffer from poorer service such as longer waiting times or deterred services, and will they suffer from lower quality of care? Since consumers can not vote on a merger,[17] how does the Commissioner, antitrust enforcer, or the courts evaluate the impact of a merger on consumers?

Insurance companies, employers, unions and buyers of insurance (''plan sponsors''), and health care providers will all have views of the impact of the merger on consumers. The views of the insurance companies can not be determinative, since they have an obligation to their stockholders to maximize profits.

The views of plan sponsors are relevant, but their failure to object to a merger may not be of significant evidentiary value. Plan sponsors represent the interests of their subscribers and thus may be concerned with the exercise of monopoly power leading to higher premiums. However, as antitrust authorities have recognized in many merger investigations, buyers of services may be very reluctant to complain about a merger for a variety of factors. They may simply pass on higher post-merger prices to the ultimate customer. In the health insurance area, although plan sponsors may be concerned about the cost of health insurance they may be less sensitive to the reduction in quality or service that may result from a merger. Finally, a customer may fear retribution post-merger.[18] This may particularly be the case in Nevada where the acquired firm will remain as the largest insurer even if the merger is denied. Thus, the fact that plan sponsors do not complain, or actually support a merger, should not be determinative of a merger's likely competitive effect.[19]

On the other hand healthcare providers may be a far more superior representative of the consumer interest and their concerns deserve careful attention. Physicians and other healthcare providers directly experience the diminution of service and quality when so-called cost containment efforts go too far. Physicians serve as advocates for the patient, especially in the often adversarial setting of managed care. Since healthcare providers experience first hand the impact of reductions in service they are more sensitive to the potential exercise of market power by health insurance. It is important to recognize in evaluating the concerns raised by providers that they are not just complaining about decreased compensation. Rather the issues raised by healthcare providers are central to concerns over quality of care: reduced services, greater waiting times, unacceptably short hospital stays, postponed or unperformed medical treatments, suboptimal alternative medical treatments, laboratory tests not performed, and other output restrictions on health services.

IV. Competitive Analysis of the United-Sierra Merger

Health Insurer Concentration: Harm to Buyers

The concentration of the health insurance industry has increased nationally due to a tremendous number of mergers and acquisitions and numerous smaller insurers exiting the industry.[20] Over the past 10 years there have been over 400 health insurer's mergers. United has acquired several firms including California-based PacifiCare Health Systems, Inc., Oxford Health Plans, and John Deere Health Plan, increasing its membership to 32 million. Similarly, WellPoint, Inc. now owns Blue Cross plans in 14 states. Together, WellPoint and United control over 33 percent of the U.S. commercial health insurance market.

This increase in concentration has not benefited consumers. Studies indicate that health insurance premiums have increased at a rate more than twice the rate of inflation or the rate of increases in workers' earnings. Average annual premium increases have ranged from 8.2% to 13.9% since 2001.[21] Moreover, since 2000, the number of employers offering health coverage benefits has decreased by nearly 10%. Studies indicated that medical benefits have not expanded despite premium increases. In contrast, health insurer profits have increased by 246% in the aggregate over the past decade.[22]

Consumers in highly concentrated health insurance markets are most vulnerable to insurance premium increases without comparable benefit increases, mirroring data of escalating health costs on the national level. One study found that more than 95% of Metropolitan Statistical Areas (MSAs) had at least one insurer in the combined HMO/PPO market with a market share greater than 30% and more than 56% of MSAs had at least one insurer with market share greater than 50%.[23] In concentrated MSAs such as these, there is a much greater likelihood that one firm, or a small group of firms, could successfully exercise market power and profitably increase prices or decrease compensation leading to less quality or service. As one prominent healthcare professor has observed in testimony before the U.S. Senate Judiciary Committee:

What is so important about the sheer number of competitors? Econometric evidence shows that in the managed care field, an increase in the number of competitors is associated with lower health plan costs and premiums; conversely, a decrease in the number of competitors is associated with increases in plan costs and premiums. The evidence also shows that the sheer number of competitors exerts a stronger influence on these outcomes than does the penetration level achieved by plans in the market.[24]

[17] Fortunately, the Commissioner has decided to hold an extensive series of hearings on the merger and provided a significant opportunity for public comment. The majority of the public comments filed by consumers to date oppose the merger.

[18] There are a wide variety of reasons why customer support of a merger may not be particularly probative. *See* Ken Heyer, Predicting the Competitive Effects of Merger by Listening to Buyers, 74 Antitrust L.L. 87 (2007); Joseph Farrell, Listening to Interested Parties in Antitrust Investigations: Competitors, Customers, Complementors, and Relativity, Antitrust. Spring 2004 at 64 (explaining why customers may support an otherwise anticompetitive merger).

[19] *See FTC* v. *H.J. Heinz Co.,* 246 F.3d 708 (D.C. Cir. 2001) (customers strongly supported merger); *United States* v. *United Tote,* 768 F. Stupp. 1064, 1084–85 (D.Del. 1991) (enjoining merger despite testimony of ''numerous buyers'' that the merger would be procompetitive in creating a stronger rival to a dominant firm); *United States* v. *Ivaco,* 704 F. Supp. 1409, 1428 (W.D. Mich. 1989)(all testifying customers supported merger); *FTC* v. *Imo Indus.,* 1992–2 Trade Cas. (CCH) ¶ 69,943, at 68,559 (D.D.C. 1989).

[20] Victoria Colliver, ''Insurer's Mergers Limiting Options: Health Care Choices Are Narrowing Says Study by AMA,'' San Francisco Chronicle, April 18, 2006 (last viewed 7/8/07) *http://sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2006/04/18/BUGUQIAH161.DTL&type=business.*

[21] Kaiser Family Foundation and Health Research and Educational Trust, Employer Health Benefits: 2006 Summary of Findings, 2006 (last viewed 7/8/2007) *http://www.kff.org/insurance/7527/upload/7528.pdf.*

[22] Laura Benko, ''Monopoly Concerns: AMA Asks Antitrust Regulators to Restore Balance,'' Modern Physician, June 1, 2006.

[23] Edward Langston, ''Statement of the American Medical Association to the Senate Committee on the Judiciary United States Senate: Examining Competition in Group Health Care,'' Sept. 6, 2006 (last viewed 7/8/07) *http://www.ama-assn.org/ama1/pub/upload/mm/399/antitrust090606.pdf.*

[24] Testimony of Professor Lawton R. Burns re. the Highmark/Independence Blue Cross Merger, before the Senate Judiciary Committee (April 7, 2007).

As we discuss below, the health insurance markets in the state of Nevada, especially Clark County, are highly concentrated, and the merger of Sierra with United is likely to substantially harm competition and consumers.

Harm to Competition in Nevada From the United-Sierra Merger

Correctly defining an economically meaningful market is essential for ensuring that consumers of that market do not become subject to market power due to increases in market concentration and decreases in competition as a result of a merger. The key question in this merger as in other mergers is the definition of the relevant product market. The courts have held that a relevant product market ''must be drawn narrowly to exclude any other product to which, within reasonable variations and price, only a limited number of buyers will turn.'' *Times-Picayune Pub. Co* v. *United States,* 345 U.S. 594, 612 n.31 (1953). Market definition focuses on demand substitution facts, and whether or not consumers would or could turn to a different product or geographic location in response to a ''small but significant non-transitory increase in price.'' [25] Typically, the antitrust agencies and the courts have implemented this test by seeking to identify the smallest group of products over which prices could be profitably increased by a ''small but significant'' amount (normally 5 percent) for a substantial period of time (normally one year).[26]

In health insurance mergers the DOJ has reached different, although not inconsistent, conclusions as to the relevant product market. For example, in the Aetna-Prudential merger DOJ concluded that the relevant product markets were the sale of health maintenance organization (''HMO'') and HMO-based point of service (''HMO–POS'') health plans. The DOJ noted that HMO and HMO–POS products differ from PPO or other indemnity products in term of benefit design cost and other factors. HMOs provide superior preventative care benefits, place limits on treatment options and generally require the use of a primary care physician ''gatekeeper.'' PPO plans are not structured in that fashion and do not emphasize preventative care. HMOs were perceived as being better devices to control costs and configure benefits. In addition, both the insurers and buyers of insurance services perceived PPOs and HMOs as being separate products. Thus. the DOJ concluded that the elasticity of demand for HMOs and HMO–POS plans are sufficiently low that a small but significant price increase for these plans would be profitable because consumers would not shift to PPO and other indemnity plans to make the increase unprofitable.

In United/PacifiCare, the DOJ defined a relevant product market as the sale of commercial health insurance to small group employers. This market consisted of employers with 2–50 employees. These employers were particularly susceptible to potential anticompetitive conduct because they lacked a sufficient employee population to self-insure and they lacked the multiple locations necessary to reduce risk through geographic diversity. In addition the manner in which commercial health insurance was sold also distinguished the small and large group markets. Large employers were more likely than smaller employers to be able to successfully engage extensive negotiations with United and PacifiCare.

We believe that both an HMO and small employer market may be adversely affected by the United-Sierra merge.[27] Surveys demonstrate that consumers do not perceive HMOs and PPOs as substitute products and consumers believe that they differ in terms of benefit design, cost, and general approaches to treatment.[28] PPOs tend to provide more flexibility in selection of physicians and specialists and tend to be more expensive. In contrast, HMOs focus more on preventative medicine but limit treatment options and require referrals from a ''gatekeeper'' for many procedures. Consumers with special health needs and those relying more on strong relationships with their physicians would generally not be satisfied if forced to subscribe to an HMO with restrictions on personal choices. ''A small but significant price increase in the premiums for HMOs and HMO–POS plans would not cause a sufficient number of customers to shift to other health insurance products to make such a price increase unprofitable.''[29]

Moreover, small employers are less likely to have significant alternatives in response to a price increase by the merged firm. Small employers are unable to self-insure and have little power to negotiate better rates.

The relevant geographic market seems to be a fairly straightforward matter since health care services are primarily local. From the perspective of the buyers of insurance services, employers want insurance where the employees work and live. Thus in Aetna/Prudential, the DOJ concluded ''the relevant geographic market in which HMO and HMO–POS plans compete are thus generally no larger than the local areas within which HMO * * * enrollees demand access to providers. * * * As a result, commercial and government health insurers—the primary purchasers of physician services—seek to have their provider network's physicians whose offices are convenient to where their enrollees work or live.''

In this merger the likely geographic markets are Clark County, Nevada and the larger geographic market of the State of Nevada. Consumers faced with an increase in prices for HMOs are unlikely to travel a long distance away from homes or places of business in order to escape price increases and purchase HMO services at a lower price. Generally, consumers are reluctant to travel lengthy distances when they are sick. Moreover, virtually all managed care companies provide networks in localities where employees live and work, and they compete with the other local networks.[30] Thus, we believe the proper relevant markets are the provision of HMO services in Clark County and Nevada.[31]

Concentration and Competitive Effects

Once the market is defined antitrust authorities and the courts calculate market shares and concentration levels (using the Herfindahl-Hirschman Index (HHI)). This merger will lead to an unprecedented level of concentration. In the Clark County HMO market United's market share will increase from 14 to 94%. If PPOs are included, United's market share increases from 9% to 60%. Regardless of how the product market is

[25] According to the Merger Guidelines, ''[a] market is defined as a product or group of products and a geographic area in which it is produced or sold such that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future seller of those products in that area would likely impose at least a 'small but significant nontransitory' increase in price, assuming the terms of sale of all other products are held constant.'' *Merger Guidelines* § 1.0.

[26] *FTC* v. *Staples,* 970 F. Supp. at 1076 n.8; *Merger Guidelines* § 1.11, at 5–6.

[27] Defining the market in terms of a single product is appropriate since the Nevada statute provides that the Commissioner can deny a merger application if she ''determines that an acquisition may substantially lessen competition *in any line of insurance* in this state or tends to create a monopoly.'' NRS 692.258(1).

[28] *See United States* v. *Aetna* Revised Complaint Impact Statement, Civil Action 3–99CV1398–H (N.D.Tex, 1999).

[29] *Id.*

[30] *Id.*

[31] As to the market for the sale of health insurance products to small employers we have no reason to believe the concentration measures differ significantly from the HMO market.

defined United is clearly a dominant firm, far larger than the post-merger market shares of the combined Aetna/Prudential or United/PacifiCare in those markets where DOJ brought enforcement actions. Even in a Nevada HMO market, the market share increases from 12% to 80% and in a Nevada HMO–PPO market United's market share increases from 7% to 48%. Simply put, post-merger United will be a dominant firm no matter how the market is defined.

Measuring concentration using the HHI leads to similar results. The Merger Guidelines define a market with an HHI over 1800 as ''highly concentrated'' and an increase over 100 is ''likely to create or enhance market power or facilitate its exercise.'' The post-merger HHI for HMOs in the state of Nevada is 4,871 and the post-merger increase in HHI is 1,625. The HMO market in Clark County is even more concentrated, with a post-merger HHI of 8,884 and a post-merger increase in HHI of 2,235. These exorbitantly high HHIs support the presumption that a merger between the two largest HMOs in the highly concentrated Nevada HMO market would likely create or enhance market power or facilitate its exercise. The market share data obtained form the Nevada State Health Division is provided below. (Figure 1).

Figure 1. Market Share Data for the HMO Market in Nevada and Clark County.[32]

Nevada			Clark County		
HMO	# patients	Market Share	HMO	Members	Market Share
Sierra Health Plan	279,679	68%	Sierra Health Plan	267,274	80%
United PacifiCare	48,196	12%	United PacifiCare	47,242	14%
Aetna	9,108	2%	Aetna	8,296	2%
WellPoint	11,365	2.70%	Nevada Care	10,639	3%
Hometown Health	23,281	6%	WellPoint	1,297	0.05%
Saint Mary's Healthfirst	27,411	7%	Total	334,748	99%
NevadaCare	10,827	2.60%			
Total	409,867	100%			

The Nevada and Clark County markets are highly concentrated, no matter how defined. The parties may suggest that this is of little import because the increase in concentration is not substantial because United currently has a relatively modest market share. Such an argument is inconsistent with the facts and the law. United is the largest health insurer in the United States and the second largest rival in the market, with the ability and incentive to expand competition. As to the law as the Supreme Court has acknowledged, ''if concentration is already great, the importance of preventing even slight increases in concentration is correspondingly great.'' [33]

As important, the combined United-Sierra will be substantially larger than its next closest rival, In the Nevada HMO market it will be over 10 times larger (80% to 7% for the second largest firm) and in the Clark County market it will be over 30 times larger (94% to 3%). The courts have recognized that smaller rivals are far less likely to constrain the conduct of a dominant firm post-merger, and have enjoined mergers with far smaller disparities in market share. *United States* v. *Phillipsburg Nat'l Bank,* 399 U.S. 350, 367 (1970) (merged firm three times the size of next largest rival); *FTC* v. *PPG,* 798 F.2d 1500, 1502–03 (D.C. Cir. 1986) (two and one-half times as large). Where a merger produces a firm that is significantly larger than its closest competitors, it increases the likelihood that the firm will be able to raise prices, decrease compensation, and reduce quality without fear that the small sellers will be able to take away enough business to defeat the price increase. *See United States* v. *Rockford Mem. Corp.,* 898 F.2d 1278, 1283–84 (7th Cir.) (Posner, J.), cert. denied, 498 U.S. 920 (1990); H. Hovenkamp, *Federal Antitrust Policy* § 12.4c (1993) (''markets may often have small niches or pockets where new firms can carve out a tiny position for themselves without having much of an effect on competitive conditions in the market as a whole'').

Combined PPO and HMO Markets

Using a definition of the health insurance product market as the combination of HMOs and PPOs, the health insurance market in Nevada is highly concentrated, and the United-Sierra merger would substantially increase the likelihood of competitive harm.

The market share for Sierra and United combined in Nevada is 48%, while in Clark County the combined United-Sierra market share is 60%. The post-merger HHI for the Nevada and Clark County markets are 3372 and 5244, respectively, The increase in the HHI market resulting from the United-Sierra merger is 555 for the State of Nevada and 921 for Clark County. Data of market shares from the Nevada State Health Division for the HMO and PPO markets is provided in Figure 2.

[32] Data provided from the Nevada State Health Division.

[33] *United States* v. *General Dynamics Corp.,* 415 U.S. 486, 497 (1974).

[34] Data from the Nevada State Health Division.

[35] The market share for WellPoint in Clark County is overstated because in the absence of data by territory, all WellPoint customers were allocated to Clark County.

Figure 2. Market Share Data for the HMO/PPO Market in Nevada and Clark County.[34]

Nevada			Clark County [35]		
Insurance Firm	Members	% Market Share	Insurance Firm	Members	Market Share
Aetna Health Inc.,	9,108	1.18%	Sierra	297,825	51.35%
Sierra Health	312,702	40.67%	WellPoint	231,971	39.99%
WellPoint	231,971	30.17%	United	50,210	8.66%
Hometown Health	99,189	12.90%	Total	580,006	100.00%
NevadaCare	20,331	2.64%			
United Pacific Care	52,456	6.82%			
Saint Mary's Health First	43,141	5.61%			
Total	768,898	100.00%			

Conclusion on the Impact of the United-Sierra Merger on Consumers

As the U.S. Supreme Court has held where a merger results in a significant increase in concentration and produces a firm that controls an undue percentage of the market, the combination is so inherently likely to lessen competition substantially that it ''must be enjoined in the absence of evidence clearly showing that the merger is not likely to have such anticompetitive effects.'' *United States* v. *Philadelphia Nat'l Bank,* 374 U.S. 321, 363 (1963), The United-Sierra merger clearly raises extraordinary and unprecedented levels of concentration which raise serious concerns about this merger. Nevada is in need of greater competition, not less. Further consolidation among the limited health plan providers in Nevada poses a substantial threat of harming customers, increasing the costs of health care, and decreasing access to quality health care and the quality of health. This merger clearly ''would likely be harmful or prejudicial to the members of the public who purchase insurance'' and thus should be denied.

V. Health Insurer Concentration: Harm to Sellers and Quality of Care

The nature of the health care industry facilitates the potential for a dominant health coverage or insurance firm to exercise market power (or monopsony) over individuals selling health care services within a geographic region. Because medical services can be neither stored nor exported, health care professionals generally must sell their services to buyers (insurance firms and their customers) in a relatively small geographic market. Refusing the terms of the dominant buyer, physicians may suffer an irrevocable loss of revenue, Consequently, a physician's ability to terminate a relationship with an insurance coverage plan depends on her ability to make up lost business by switching to an alternative insurance coverage plan. Where those alternatives are lacking a physician may be forced to reduce the level of service in response to a decrease in compensation.

Not all insurance providers are equal from the perspective of a health care provider. A smaller insurance company with fewer covered lives may not he an attractive alternative. Health care providers who depend on an insurance program for all or most of their income are at a substantial disadvantage when there are not competing programs available; when they switch programs, they tend to lose the patients who have that particular coverage, It makes little sense for a provider to switch to an insurer who has a substantially smaller market share because there won't be enough patients to sustain the practice. Thus, it is critical for insurance regulators to maintain a competitive market in which health care providers have significant competitive alternatives.

In the Aetna/Prudential and United/PacifiCare mergers, the DOJ raised monopsony concerns in markets for purchasing physicians' services where the market shares were far less substantial than they are in Clark County. For example, in United/PacifiCare the DOJ alleged that the combined firm would account for an excess of 35% in Tucson and over 30% in Boulder.

In addition, it is important to recognize that it may be appropriate to prevent a firm from securing monopsony power even if it faces a competitive downstream market. In other words there may be antitrust concerns if a health insurer can lower compensation to providers even if it can not raise prices to consumers. For example, in United/PacifiCare the Division required a divestiture based on monopsony concerns in Boulder even though United/PacifiCare would not necessarily have had market power in the sale of health insurance. The reason is straightforward—the reduction in compensation would lead to diminished service and quality of care, which harms consumers even though the direct prices paid by subscribers do not increase.[36]

Underlying the monopsony analysis in these cases is the premise that physicians who have a large share of reimbursements from the merged firm lack alternatives in response to a reduction in compensation. As alleged in Aetna, they cannot retain or timely replace a sufficient portion of those payments if the physicians stop participating in the plans. Moreover, it is difficult to convince patients to switch to different plans.[37] Consequently, according to the Division these physicians would not be in a position to reject a ''take it or leave it'' contract offer and could be forced to accept low reimbursement rates from a merged entity, likely leading to a reduction in quantity or degradation in quality of physician services.

The merging parties may suggest that there is some safe harbor for mergers leading to a market share below 35%. As the DOJ enforcement action in Boulder demonstrates that is not the case. The unique nature of health care provider services explains why monopsony concerns are raised at lower levels of concentration than may be appropriate in other industries. If a health care provider's output is suppressed by a reduction in compensation, then it is a lost sale that

[36] See Marius Schwartz, Buyer Power Concerns andthe *Aetna-Prudential Merger,* Address Before the 5thAnnual Health Care Antitrust Forum at Northwestern University School of Law 4–6 (October 20, 1999) (noting that anticompetitive effects can occur even if the conduct does not adversely affect the ultimate consumers who purchase the end-product), *available at http://www.usdoj.gov/atr/public/speeches/3924.wpd.*

[37] As alleged in the United complaint, physicians encouraging patients to change plans ''is particularly difficult for patients employed by companies that sponsor only one plan because the patient would need to persuade the employer to sponsor an additional plan with the desired physician in the plans's network'' or the patient would have to use the physician on an out-of-network basis at a higher cost. Complaint at paragraph 37.

cannot be recovered later. Physician services can not be stored for later sale. As the DOJ observed in United/PacifiCare: ''A physician's ability to terminate a relationship with a commercial health insurer depends on his or her ability to replace the amount of business lost from the termination, and the time it would take to do so. Failing to replace lost business expeditiously is costly.'' [38] The DOJ observed that there are limited outlets for physician services: ''There are no purchasers to whom physicians can sell their services other than individual patients or the commercial and governmental health insurers that purchase physician services on behalf of their patients.'' [39] As a former DOJ official observed ''these factors explain why the Department concluded that shares below 35 percent, in the particular markets at issue, sufficed to allege competitive harm.'' [40]

Again the proponents of health insurance mergers may suggest that regulators should take a benign view about the creation of monopsony power because health insurers are ''buyers'' acting in the interest of reducing prices. As we suggested earlier this view is mistaken. Health insurers are not true fiduciaries for insurance subscribers. Plan sponsors may have a limited concern over the product based on the cost of the insurance, and not the quality of care. Furthermore, health coverage plans operate in the interest of a group, not in the best interest of individual patients. Consequently, insurance firms can increase profits by reducing the level of service and denying medical procedures that physicians would normally perform based on professional judgment. In the absence of competition among insurers, patients are more likely to pay for these procedures out-of-pocket or forego them entirely. Ultimately, the creation of monopsony power from a merger can adversely impact both the quantity and quality of health care.

Finally, the evidence from mergers throughout the U.S. strongly suggests that the creation of buyer power from health insurance consolidation has not benefited competition or consumers. Although compensation to providers has been reduced health insurance premiums have continued to increase rapidly. Moreover, evidence from other mergers suggests that insurers dot not pass savings on from these mergers to consumers. Rather, insurance premiums increase along with insurance company profits.

Monopsony in the Health Care Markets of Nevada

United's acquisition of Sierra would give it unique control over the physicians serving the HMO and HMO-PPO markets in Clark County and the State of Nevada. The merger will combine the two largest HMOs with an 84% market share in Nevada and a 90% market share in Clark County, dramatically higher than the concentration in any merger approved by the DOJ. In light of these high market shares, a physician faced with unfair contract terms could not credibly threaten to leave the combined United-Sierra health plan, except by departing Clark County.

The parties have suggested the markets for physician reimbursement are far less concentrated. At the earlier hearing they suggested the merged firm would account for only 17% of physician reimbursement in the state and 21% in Clark County. We do not know the basis for the claimed reimbursement percentages. One should take United's estimates of market shares with a large grain of salt. In United/PacifiCare their lawyers suggested the parties' total share of physicians' reimbursement likely were substantially below the 35% threshold, but those estimates were rejected by DOJ. As one of their advocates said ''indeed the parties calculated their total shares of physician reimbursements in the Tucson and Boulder MSAs were substantially lower than the shares asserted in the complaint.'' [41] The estimates of the proponents in the Aetna/Prudential merger were also rejected by the DOJ.[42]

Monopsony power exercised by HMOs and health insurance plans, like high medical malpractice insurance premiums, has the potential to drive health care professionals out of geographic regions and even into other professions. The Nevada health care market currently faces one of the largest shortages of doctors and nurses in the country.[43] It ranks 49th of the 50 states in physician coverage. Shortages of health care professionals can become a vicious cycle admonishing others against entering the profession. Doctor shortages increase with shortages of nurses and increases in insurance costs.[44] Nationally, it has become less attractive to become a physician because of the enormous cost associated with medical education, long years of schooling and residencies, and increased difficulty in earning a living.[45] Recently, Nevada has implemented programs to attract doctors from Mexico and train doctors in Mexico at the Universidad Autonoma de Guadelajara.[46]

Similar problems exist in nursing. Understaffed nursing departments require nurses to work overtime, work more holiday shifts, and undertake more responsibilities. These conditions exacerbate protracted work-related stress and decrease the attractiveness of working as a nurse in Nevada. Moreover, reduced flexibility for time off and patient dissatisfaction resulting from overworked nurses is generally associated with lower levels of job satisfaction and higher turnover rates.[47]

[38] Complaint, at paragraph 36.

[39] Complaint, at paragraph 33.

[40] Mark Botti, Remarks before the ABA Antitrust Section, ''Observations on and from the Antitrust Division's Buyer-Side Cases: How Can ''Lower'' Prices Violate the Antitrust Laws.'' He also noted that: ''Physicians have a limited ability to maintain the business of patients enrolled in a health plan once the physician terminates. Physicians could retain patients by encouraging them to switch to another health plan in which the physician participates. This is particularly difficult for patients employed by companies that sponsor only one plan because the patient would need to persuade the employer to sponsor an additional plan with the desired physician in the plan's network. Alternatively, the patient may remain in the plan, visiting the physician on an out-of-network basis. The patient would be faced with the prospect of higher out-of-pocket costs, either in the form of increased co-payments for use of an out-of-network physician, or by absorbing the full cost of the physician care.'' Complaint at paragraph 37.

[41] Fiona Schaeffer *et al.*, ''Diagnosing Monopsony and other issues in Health Care Mergers: an overview of United/PacifiCare Investigation,'' Antitrust Health Care Chronicle (2006).

[42] The estimates of the level of physician reimbursement by the proponents of the Aetna/Prudential merger were also rejected by the DOJ. The proponents suggested that the total amount of physician revenues affected by the merger were far less than thirty percent according to public available data. According to the proponents the merged firm would have accounted for about 20% of total physician revenues in Houston and about 25% of total physician revenues in the Dallas-Fort Worth area after the transaction. In addition, there were 14 HMOs in the Houston area and 12 HMOs in Dallas. *See* Robert E. Bloch et al. ''A New and Uncertain Future for Managed Care Mergers: An Antitrust Analysis of the Aetna/Prudential Merger.'' Yet the DOJ required an enforcement action to address monopsony concerns in spite of these alleged low shares of reimbursement.

[43] *See* Lawrence Mower, ''Help Sought South of the Border,'' *Las Vegas Review Journal,* Jan. 22, 2007; *see also* Lenita Powers, ''Big Day at Lawlor,'' *Reno Gazette,* Dec. 9, 2006 (expressing that nurses in Nevadaare in a desperately short supply, especially OR nurses).

[44] *See* Lawrence Mower, ''Help Sought South of the Border,'' *Las Vegas Review Journal,* Jan. 22, 2007.

[45] Lawrence Mower, ''Help Sought South of the Border,'' *Las Vegas Review Journal,* Jan. 22, 2007.

[46] *Id.*

[47] *See* Jennifer Kettle, *Factors Affecting Job Satisfaction in the Registered Nurse, Journal of Undergraduate Nursing Scholarship,* Fall 2002 (last viewed July 9, 2007) *http://www.juns.nursing.arizona.edu/articles/Fall%202002/Kettle.htm.*

VI. Conclusion on the Impact of the United-Sierra Merger on Health Care Professionals and Quality of Care

The United-Sierra merger poses a substantial threat to competition leading to reduced compensation for health care professionals who may be forced to reduce service and quality of care. This reduced quality of care ''would likely be harmful or prejudicial to the members of the public who purchase insurance.'' Further consolidation in the HMO and health coverage markets in Nevada may have detrimental short-term and long-term effects by exacerbating the crisis of the health professional shortage. Competition is essential to the delivery of high quality health care services. The United-Sierra merger will further distort the already concentrated and inefficient Nevada health care market.

Barriers to Entry Are High

As noted earlier, entry can be a factor in the analysis of a merger that may reverse the presumption of anticompetitive effects. The courts have required that ''entry into the market will likely avert the anticompetitive effects from the acquisition.'' *FTC* v. *Staples,* 970 F. Supp. 1066, 1086 (D.D.C, 1997). Entry must be ''timely, likely insufficient in its magnitude, character and scope to deter or counteract the competitive effects'' of a proposed acquisition. Merger Guidelines § 3.0.

The barriers to entry in the HMO and health insurance markets in Nevada and Clark County are very high. There has been relatively little recent entry into either Clark County or Nevada. The fact that United, the largest health insurer in the U.S., chose to enter into Nevada through two acquisitions —PacifiCare and Sierra—suggests the significant difficulty of de novo entry in these markets.

Generally, entry into health insurance markets is difficult. The health care industry does not fit the traditional model of perfect competition as expounded by the Chicago School.[48] For example there is a high degree of ''lock-in'' because plan sponsors cannot disrupt the medical treatment of countless employee/patients. New entrants are vulnerable to the high switching costs that characterize the health insurance industry. Many consumers have no choice for health coverage plans and must accept the plan provided by an employer. Other consumers can only switch during an ''open enrollment'' season. Doctors cannot easily switch their patients to a different health plan and, in the absence of a large number of patients enrolled in a plan, a doctor may find that additional claim processing costs exceed the benefits of carrying an additional health coverage provider. Similarly, doctors may be reluctant to switch plans because earnings lost in pursuit of new patients and alternate third-party payers may lead to exorbitant losses.[49]

Developing an HMO from scratch requires extensive expenditure on recruiting and maintaining health professionals, developing computer information systems and data banks, and high expenditures on overhead and clinical facilities. De novo entry is very challenging since new entrants must develop a reputation and product recognition with purchasers to convince them to disrupt their current relationships with the dominant health insurers.[50] As a recent DOJ/FTC report on health care competition reported, there has been relatively little de novo entry by national health insurers.[51]

Not surprisingly the DOJ has recognized the substantial barriers to entry and expansion in health insurance markets. In the Aetna/Prudential merger, the DOJ found substantial entry barriers. Certainly Dallas and Houston were attractive markets for health insurers. Both markets had a substantial number of alternative health insurers capable of expansion. And there were numerous competitors in other Texas markets that were capable of entering into these markets. Yet the DOJ found substantial entry barriers and that entry could take two to three years and cost up to $50 million.[52] In particular it found that it was ''unlikely that a company that currently provides PPO or indemnity health insurance in either Dallas or Houston would shift its resources to provide an HMO or HMO-POS plan'' in either market.[53]

Entry barriers are even more substantial in Nevada and Clark County. The shortage of health care professionals in Nevada increases barriers to entry because new entrants are unlikely to be able to contract with an adequate number of health professionals to attract new plan sponsors and enrollees. Moreover, when a dominant HMO maintains a high market share, other health providers may perceive or experience higher rates of adverse selection, moral hazard, and general vulnerability to tactics by a dominant HMO to raise rival's cost.[54] Experience indicates that new HMOs have not historically entered highly concentrated markets after a merger occurs.

The parties may also suggest that some of the smaller HMOs and health insurance providers in Nevada may be able to expand post-merger to prevent any anticompetitive effects. This is extremely unlikely because the fringe firms are currently so extremely small and far smaller than a combined United-Sierra. In cases with an even far smaller size disparity between the merged and fringe firms courts have declined to find that small players might suddenly expand to constrain a price increase by leading firms. *United States* v. *Philadelphia Nat'l Bank,* 374 U.S., 321, 367 (1963); *United States* v. *Rockford Mem. Corp.,* 898F.2d. 1278, 1283–84 (7th Cir. 1990) (''three firms having 90 percent of the market can raise prices with relatively little fear that the fringe of competitors will be able to defeat the attempt by expanding their own output to serve customers of the three large firms'').

The small firm expansion claim was rejected by the DOJ in Aetna/Prudential, a case with far smaller post-merger market shares and a far greater number of fringe firms:

Due not only to these costs and difficulties, but also to advantages that Aetna and Prudential hold over their existing competitors—including nationally recognized quality accreditation, product array, provider network and national scope and reputation—existing HMO and HMO-POS competitors in Dallas or Houston are unlikely to be able to expand or reposition themselves sufficiently to

[48] *See* Thomas Greaney, *Chicago's Procrustean Bed; Applying Antitrust Law in Health Care,* 71 Antitrust L.J. 857 nl (2004) (''Perfectly competitive markets demonstrate the following four characteristics: (1) Perfect product homogeneity (2) large numbers of buyers and sellers (3) perfect knowledge of market conditions by all market participants and (4) complete mobility of all product resources.'')

[49] Moreover, most employee/patients are limited to the physicians within the plan sponsors contract.

[50] At the FTC/DOJ Health Care hearings, a former Missouri Commissioner of Insurance suggested that new entrants ''face a Catch 22—they need a large provider network to attract customers, but they also need a large number of customers to obtain sufficient price discounts from providers to be competitive with the incumbents.'' In addition, he observed that there is a first mover, or early mover, advantage in the HMO industry, possibly resulting in later entrants having a worse risk pool from which to recruit members. He also observed reputation may inhibit entry. *See Improving Health Care: A Dose of Competition,* A Report by the Federal Trade Commission and the Department of Justice, Chapter 6 at 10 (July 2004), *available at http://www.usdoj.gov/atr/public/health_care/204694/chapter6.htm#3.*

[51] *Id.* at 11 (citing testimony that the only successful entry of national plans has been by purchasing hospital-owned local health plans).

[52] In light of the health professional shortage in Nevada, these values could be understated.

[53] Complaint at paragraph 23.

[54] *See* Roger Noll, *Buyer Power and Antitrust: ''Buyer Power'' and Economic Policy,* 72 Antitrust L.J. 589, 2005.

restrain anticompetitive conduct by Aetna in either of these geographic markets.[55]

History demonstrates that one can not rely on new entry in Clark County. Few competitors from the rest of Nevada have been able to successfully enter Clark County. Attempting to enter into a market dominated by a single firm is a daunting task. There may be several obstacles to expansion including cost disadvantages, efficiencies of scale and scope and reputational barriers. In other mergers, the courts have found these types of impediments to be significant barriers to entry and expansion. For example, in the FTC's successful challenge to mergers of drug wholesalers the court noted: ''[t]he sheer economies of scale and scale and strength of reputation that the Defendants already have over these wholesalers serve as barriers to competitors as they attempt to grow in size.'' [56]We believe similar obstacles exist for potential entrants in these markets.

Relying on promises of entry and expansion may be a risky path for competition and consumers. In recent FTC/DOJ health care hearings, a former Missouri Commissioner of Insurance discussed several HMO mergers that his office approved based on the parties' arguments that entry was easy, that there were no capacity constraints on existing competitors (there were at least ten HMO competitors), and that any of the 320 insurers in the state could easily enter the HMO market. Unfortunately, those predictions were mistaken and there has been no entry in the St. Louis HMO market since the mid-1990s.[57] This experience should make any regulator cautious about relying on predictions of new entry.

Efficiencies of the United-Sierra Merger Are Minimal

The parties have not suggested that there are significant efficiencies that may result from the merger. Under the Nevada statute, the Commissioner can consider efficiencies that either ''create[ ] substantial economies of scale or economies in the use of resources that may not be created in any other manner'' or ''substantially increase[ ] the availability of insurance.'' [58] In either case, the public benefit of either of these efficiencies must exceed the loss of competition. This standard simply can not be met in this case where the merger creates a dominant firm.

As a matter of U.S. merger law, efficiencies can justify an otherwise anticompetitive merger in very limited circumstances. Those efficiencies which are considered under the antitrust laws are solely those efficiencies which lead to improvements for consumers in terms of lower prices, greater innovation or greater service and quality. Moreover, an efficiency must be merger specific—that is it can not be achieved in any less anticompetitive fashion. When a cost savings does not result in those benefits to consumers it is not properly considered.

The record on recent health insurance mergers does not suggest that these mergers have led to substantial benefits to consumers in lower prices, better quality of care or service. Despite the occurrence of hundreds of health insurance mergers that have occurred in the past decade, subscriber premiums have continued to rise at twice the rate of inflation and physician fees.[59] Health benefits have not expanded with subscriber premiums.[60] Consequently, the efficiencies in health insurance mergers deserve careful scrutiny and a heavy dose of skepticism.[61]

The actual record on efficiencies from health insurance mergers is spotty at best. As Professor Lawton Burns has observed in Congressional testimony:

[T]he recent historical experience with mergers of managed care plans and other types of enterprises does not reveal any long-term efficiencies.

[E]ven in the presence of [efforts to achieve cost-savings] and defined post-integration strategies, scale economies and merger efficiencies are difficult to achieve. The econometric literature shows that scale economies in HMO health plans are reached at roughly 100,000 enrollees. * * * Moreover, the provision of health insurance (e.g., front-office and back-office functions) is a labor-intensive rather than capital-intensive industry. As a result, there are minimal economies to reap as scale increases. * * * Finally, there is little econometric evidence for economies of scope in these health plans—e.g., serving both the commercial and Medicare populations. Serving these different patient populations requires different types of infrastructure. Hence, few efficiencies may be reaped from serving large and diverse client populations. Indeed, really large firms may suffer from diseconomies of scale.[62]

United's actual record in achieving efficiencies is a mixed one at best. Bigger is not necessarily better and a national platform is not better than a local one. To provide just one example, United completely disrupted efficient working relationships between University Medical Center and PacifiCare by replacing the local insurer's claims processing with a more bureaucratic national one.[63] This disruption in working operations increased the number of unpaid claims and created other problems with provider services. One need look no further than United's track record for inadequate claims processing over the past five years.

- The Nebraska Department of Insurance, which imposed a fine of $650,000, the largest ever, on United Health for inadequately handling complaints, grievance, and appeals.
- In March 2006, the Arizona Department of Insurance fined United $364,750 for violating state law by denying services and claims, delaying payment to providers and failing to keep proper records.
- In December 2005, the Texas Department of Insurance fined United $4 million for failing to pay promptly, lacking accurate claim data reports and not maintaining adequate complaint logs. The insurance giant also had to pay restitution to physicians.[64]

State imposed fines are an inadequate remedy for poor services to patients and doctors. First, the actual payer of these fines is the consumer, because United

[55] Complaint at paragraph 24. In Aetna, thepost-merger market shares were 44% and 62% and there were between 10-12 smaller competitors capable of expansion. In this case, the post-merger market share is greater than 90% and there are a handful of smaller competitors.

[56] *FTC* v. *Cardinal Health, Inc.,* 12 F. Supp. 34, 57 (D.D.C. 1998); see *United States* v. *Rockford Memorial Hosp.,* 898 F.2d 1278, 1283–84 (7th Cir. 1990) (''the fact [that fringe firms] are so small suggests that they would incur sharply rising costs in trying almost to double their output * * * it is this prospect which keeps them small'').

[57] Testimony of Jay Angoff, former Missouri Commissioner of Insurance, before the FTC/DOJ Healthcare Hearings, April 23, 2003 at 40–45, discussed at *Improving Health Care: A Dose of Competition.* A Report by the Federal Trade Commission and the Department of Justice, Chapter 6 at 10 (July 2004), available at *http://www.usdoj.gov/atr/public/health_care/204694/chapter6.htm#3.*

[58] NRS 692C.256(3).

[59] Laura Benko, ''Monopoly Concerns: AMA Asks Antitrust Regulators to Restore Balance,'' *Modern Physician,* June 1, 2006.

[60] Best Wire, ''Study Says Competition in Health Markets Waning,'' *Best Wire* Apr. 19, 2006.

[61] *See* Laura Benko, ''Bigger Yes, But Better?'' *Modern Health Care,* March 19, 2007.

[62] Testimony of Professor Lawton R. Burns re. the Highmark/Independence Blue Cross Merger, before the Senate Judiciary Committee (April 7, 2007).

[63] *See* Laura Benko, ''Bigger Yes, But Better?'' Modern Health Care, March 19, 2007.

[64] Marshall Allan, ''Insurer Comes Here With a Trail of Fines From Other States,'' Las Vegas Sun, June 20, 2007.

can pass these fines off to consumers in the form of higher premiums and co-payments. Second, fines pose no solace to patients that may suffer the persistent hounding from creditors as a result of unpaid insurance claims. Further consolidation will only enhance the likelihood of shoddy claims service since consumers will have few rivals to turn to in response to poor quality of service.

United may suggest the merger is procompetitive because it will lead to improved cost containment initiatives. Of course, Sierra may adopt those measures without a merger. In addition, although efforts to contain costs are rooted in legitimate needs, the actual implementation of cost containment efforts can produce negative consequences for the quality of health care provided to consumers. However, most cost containment efforts center on decreasing utilization. Moreover, in concentrated markets, the likelihood of administered pricing and agreements not to reimburse for a procedure is more likely. Ultimately, the insurer's gross margin increases by reducing access to care and the quality of care for consumers.

The burden should be on the merging parties to demonstrate that the efficiencies they put forward are not speculative, that they exceed the likely anticompetitive effects on consumers and suppliers of services, and that the benefits will be passed on in the form of lower premiums and better quality, rather than larger profits for shareholders. It is highly unlikely that burden can be met in this case.

Recommendations

The United-Sierra merger poses a serious threat to competition in the provision of insurance and health care services in Nevada, especially Clark County. This merger requires heightened scrutiny given the currently high concentration of the health coverage providers in the Nevada market and the current shortage of health care professionals in the State. The merger should be denied because it ''would * * * substantially lessen competition in insurance in Nevada or tend to create a monopoly,'' through the creation of a dominant health insurance provider particularly in Clark County. Moreover, it will lead to a reduction in the level and quality of service thus harming and prejudicing ''the members of the public who purchase insurance.'' Enhancement of Nevada's health care requires increased levels of competition and greater market efficiency, which cannot be achieved through a merger between two of the State's largest health insurance providers. The likelihood of competitive harms from the United-Sierra merger is substantial, and the procompetitive benefits *de minimus.* Pursuant to NRS 692C.258(1), we urge the Commissioner to deny the merger application.

[FR Doc. E8–17366 Filed 8–21–08; 8:45 am]

BILLING CODE 4410–11–M

Federal Register

Friday,
August 22, 2008

Part V

Department of Labor

Employee Benefits Security Administration

29 CFR Parts 2550

Investment Advice—Participants and Beneficiaries; Proposed Class Exemption for the Provision of Investment Advice to Participants and Beneficiaries of Self-Directed Individual Account Plans and IRAs; Proposed Rule; Notice

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

RIN 1210–AB13

Investment Advice—Participants and Beneficiaries

AGENCY: Employee Benefits Security Administration, DOL.

ACTION: Proposed rule.

SUMMARY: This document contains proposed regulations implementing the provisions of the statutory exemption set forth in sections 408(b)(14) and 408(g) of the Employee Retirement Income Security Act, as amended (ERISA or the Act), and parallel provisions in the Internal Revenue Code of 1986, as amended (Code), relating to the provision of investment advice described in the Act by a fiduciary adviser to participants and beneficiaries in participant-directed individual account plans, such as 401(k) plans, and beneficiaries of individual retirement accounts (and certain similar plans). Section 408(b)(14) provides an exemption from certain prohibited transaction provisions in ERISA with respect to the provision of investment advice, the investment transaction entered into pursuant to the advice, and the direct or indirect receipt of fees or other compensation by the fiduciary adviser or an affiliate in connection with the provision of advice or the transaction pursuant to the advice. Section 408(g) describes the conditions under which the investment advice-related transactions are exempt. Upon adoption, the regulations will affect sponsors, fiduciaries, participants and beneficiaries of participant-directed individual account plans, as well as providers of investment and investment advice-related services to such plans.

DATES: Written comments on the proposed regulations should be submitted to the Department of Labor on or before October 6, 2008.

ADDRESSES: To facilitate the receipt and processing of comment letters, the Employee Benefits Security Administration (EBSA) encourages interested persons to submit their comments electronically by e-mail to *e-ORI@dol.gov* (Subject: Investment Advice Regulations), or by using the Federal eRulemaking portal at *http://www.regulations.gov* (follow instructions for submission of comments). Persons submitting comments electronically are encouraged not to submit paper copies. Persons interested in submitting paper copies should send or deliver their comments to the Office of Regulations and Interpretations, Employee Benefits Security Administration, Attn: Investment Advice Regulations, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. All comments will be available to the public, without charge, online at *http://www.regulations.gov* and *http://www.dol.gov/ebsa* and at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Fred Wong, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

Section 3(21)(A)(ii) of ERISA includes within the definition of ''fiduciary'' a person that renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of a plan, or has any authority or responsibility to do so.[1] The prohibited transaction provisions of ERISA and the Code prohibit an investment advice fiduciary from using the authority, control or responsibility that makes it a fiduciary to cause itself, or a party in which it has an interest that may affect its best judgment as a fiduciary, to receive additional fees. As a result, in the absence of a statutory or administrative exemption, fiduciaries are prohibited from rendering investment advice to plan participants regarding investments that result in the payment of additional advisory and other fees to the fiduciaries or their affiliates.

With the growth of participant-directed individual account plans, there has been an increasing recognition of the importance of investment advice to participants and beneficiaries in such plans. Over the past several years, the Department of Labor (Department) has issued various forms of guidance concerning when a person would be a fiduciary by reason of rendering investment advice and when the provision of investment advice might result in prohibited transactions.[2] Most recently, Congress and the Administration, responding to the need to afford participants and beneficiaries greater access to professional investment advice, amended the prohibited transaction provisions of ERISA and the Code, as part of the Pension Protection Act of 2006 (PPA),[3] to permit a broader array of investment advice providers to offer their services to participants and beneficiaries responsible for investment of assets in their individual accounts and, accordingly, for the adequacy of their retirement savings.

Specifically, section 601 of the PPA added a statutory exemption under sections 408(b)(14) and 408(g) of ERISA. Parallel provisions were added to the Code at section 4975(d)(17) and 4975(f)(8).[4] Section 408(b)(14) sets forth the investment advice-related transactions that will be exempt from the prohibitions of section 406 if the requirements of section 408(g) are met. The transactions described in section 408(b)(14) are: The provision of investment advice to the participant or beneficiary with respect to a security or other property available as an investment under the plan; the acquisition, holding or sale of a security or other property available as an investment under the plan pursuant to the investment advice; and the direct or indirect receipt of compensation by a fiduciary adviser or affiliate in connection with the provision of investment advice or the acquisition, holding or sale of a security or other property available as an investment under the plan pursuant to the investment advice.

On December 4, 2006, the Department published a Request for Information (RFI) in the **Federal Register** soliciting information to assist the Department in the development of regulations under sections 408(b)(14) and 408(g).[5] Specifically, the Department invited interested persons to address the qualifications for the ''eligible

[1] See also Code section 4975(e)(3)(B); 29 CFR 2510.3–21(c).

[2] See Interpretative Bulletin relating to participant investment education, 29 CFR § 2509.96–1 (Interpretive Bulletin 96–1); Advisory Opinion (AO) 2005–10A (May 11, 2005); AO 2001–09A (December 14, 2001); and AO 97–15A (May 22, 1997).

[3] Public Law 109–280, 120 Stat. 780 (Aug. 17, 2006).

[4] Under Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978), 5 U.S.C. App.1, 92 Stat. 3790, the authority of the Secretary of the Treasury to issue rulings under section 4975 of the Code has been transferred, with certain exceptions not here relevant, to the Secretary of Labor. Therefore, the references in this notice to specific sections of ERISA should be taken as referring also to the corresponding sections of the Code.

[5] 71 FR 70429, Dec. 4, 2006. The Department, on the same date, also published a Request for Information in the **Federal Register** soliciting information to assist the Department in determining the feasibility of using computer models in connection with individual retirement accounts, as required by PPA section 601(b)(3). 72 FR 70427, Dec. 4, 2006.

investment expert'' that is required to certify that computer models used in connection with the statutory exemption meet the requirements of the statutory exemption. The Department also invited interested persons to provide information to assist the Department in developing procedures to be followed in certifying that a computer model meets the requirements of the statutory exemption. The Department also invited suggestions for a model disclosure form for purposes of the statutory exemption. In response to the RFI, the Department received 24 letters addressing a variety of issues presented by the statutory exemption. These comments have been taken into account in developing the proposed regulations.

On February 2, 2007, the Department issued Field Assistance Bulletin 2007–01 addressing certain issues presented by the new statutory exemption. This Bulletin affirmed that the enactment of sections 408(b)(14) and (g) did not invalidate or otherwise affect prior guidance of the Department relating to investment advice and that such guidance continues to represent the views of the Department.[6] The Bulletin also confirmed the applicability of the principles set forth in section 408(g)(10) [Exemption for plan sponsor and certain other fiduciaries] to plan sponsors and fiduciaries who offered investment advice arrangements with respect to which relief under the statutory exemption is not required. Finally, the Bulletin addressed the scope of the fee-leveling requirement for purposes of an eligible investment advice arrangement described in section 408(g)(2)(A)(i). The Department's views on that issue are set forth in the discussion of the proposed regulations that follows.

The proposed regulations contained in this notice would, upon adoption, implement the provisions of the statutory exemption for the provision of investment advice to participants and beneficiaries under sections 408(b)(14) and 408(g). In this regard, the Department notes that, in an effort to ensure broad availability of investment advice to both participants and beneficiaries in individual account plans and beneficiaries with individual retirement accounts, the Department also is publishing a proposed class exemption for the provision of investment advice to such individuals. The proposed class exemption appears in the Notice section of today's **Federal Register**.

B. Overview of Proposed § 2550.408g–1

1. General

In general, proposed § 2550.408g–1 tracks the requirements under section 408(g) that must be satisfied in order for the investment advice-related transactions described in section 408(b)(14) to be exempt from the prohibitions of section 406.

Paragraph (a) of the proposal sets forth the general scope of the statutory exemption and regulation as providing relief from the prohibitions of section 406 of ERISA for transactions described in section 408(b)(14) of ERISA in connection with the provision of investment advice to a participant or a beneficiary if the investment advice is provided by a fiduciary adviser under an ''eligible investment advice arrangement.'' Paragraph (a) also notes that the Code contains parallel provisions at section 4975(d)(17) and (f)(8).

Paragraph (b) of the proposal provides that, for purposes of sections 408(g)(1) of ERISA and section 4975(f)(8) of the Code, an ''eligible investment advice arrangement'' shall mean an arrangement that meets either the requirements of paragraph (c) [describing investment advice arrangements that use fee-leveling] or paragraph (d) [describing investment advice arrangements that use computer modeling] of the proposal or both.

2. Fee-Leveling

With respect to arrangements that use fee-leveling, paragraph (c) of the proposal requires that any investment advice be based on generally accepted investment theories that take into account the historic returns of different asset classes over defined periods of time, although nothing in the proposal is intended to preclude investment advice from being based on generally accepted investment theories that take into account additional considerations. Paragraph (c) also requires that any investment advice take into account information furnished by a participant or beneficiary relating to age, life expectancy, retirement age, risk tolerance, other assets or sources of income, and investment preferences, although nothing in the proposal is intended to preclude a fiduciary adviser from taking into account additional information that a participant or beneficiary may provide. While section 408(g)(2)(A)(i) does not specifically reference such conditions, the principles are so fundamental to the provision of informed, individualized investment advice that a failure on the part of a plan fiduciary to insist on such conditions in the selection of an investment adviser for plan participants would, in the Department's view, raise serious questions as to the fiduciary's exercise of prudence. For this reason, the Department determined that such conditions are sufficiently significant that they should be included in the regulation implementing the statutory exemption for investment advice.

With regard to compensation and fees for the provision of investment advice, paragraph (c)(1)(iii) provides that any fees or other compensation (including salary, bonuses, awards, promotions, commissions or other things of value) received, directly or indirectly, by *any employee, agent or registered representative that provides investment advice on behalf of a fiduciary adviser* does not vary depending on the basis of any investment option selected by a participant or beneficiary. Paragraph (c)(1)(iv) provides that any fees (including any commission or other compensation) received by *the fiduciary adviser* for investment advice or with respect to the sale, holding, or acquisition of any security or other property for purposes of investment of plan assets do not vary depending on the basis of any investment option selected by a participant or beneficiary.

The individual compensation requirement in paragraph (c)(1)(iii) is designed to safeguard against a firm's creation of incentives for individuals to recommend certain investment products. It appears that, while an individual may have a general interest in the overall success of his or her employing firm, this interest, by itself, would not be inconsistent with the individual compensation requirement. This would not be the case, however, if the individual's direct or indirect compensation or benefits vary based on the selection of particular investment options. In order to determine whether more precise guidance can be developed, we request public comment on the types and formulations of direct and indirect compensation arrangements being utilized, and how they may operate under this provision.

[6] In this regard, the Department cited the following: August 3, 2006 Floor Statement of Senate Health, Education, Labor and Pensions Committee Chairman Enzi (who chaired the Conference Committee drafting legislation forming the basis of H.R. 4), regarding investment advice to participants in which he states, ''It was the goal and objective of the Members of the Conference to keep this advisory opinion [AO 2001–09A, SunAmerica Advisory Opinion] intact as well as other pre-existing advisory opinions granted by the Department. This legislation does not alter the current or future status of the plans and their many participants operating under these advisory opinions. Rather, the legislation builds upon these advisory opinions and provides alternative means for providing investment advice which is protective of the interests of plan participants and IRA owners.'' 152 Cong. Rec. S8,752 (daily ed. Aug. 3, 2006) (statement of Sen. Enzi).

With regard to the foregoing, the Department, in interpreting the scope of the fee-leveling requirement for purposes of section 408(g)(2)(A)(i), expressed its view, in Field Assistance Bulletin 2007–01 (February 2, 2007), that only the fees or other compensation of the fiduciary adviser may not vary. In contrast to other provisions of section 408(b)(14) and section 408(g), the Department explained, section 408(g)(2)(A)(i) references only the fiduciary adviser, not the fiduciary adviser or an affiliate. Inasmuch as a person, pursuant to section 408(g)(11)(A), can be a fiduciary adviser only if that person is a fiduciary of the plan by virtue of providing investment advice, an affiliate of a registered investment adviser, a bank or similar financial institution, an insurance company, or a registered broker dealer will be subject to the varying fee limitation only if that affiliate is providing investment advice to plan participants and beneficiaries. The Department further noted that, consistent with past guidance, if the fees and compensation received by an affiliate of a fiduciary that provides investment advice do not vary or are offset against those received by the fiduciary for the provision of investment advice, no prohibited transaction would result solely by reason of providing investment advice and thus there would be no need for a prohibited transaction exemption.[7] The Department, therefore, concluded that Congress did not intend for the requirement that fees not vary depending on the basis of any investment options selected to extend to affiliates of the fiduciary adviser, unless, of course, the affiliate is also a provider of investment advice to a plan. This continues to be the view of the Department.

The Department also noted in the Bulletin that, although section 408(g)(11)(A) generally limits ''fiduciary advisers'' to certain types of entities, it also permits employees, agents, or registered representatives of those entities to also qualify as fiduciary advisers if they satisfy the requirements of applicable insurance, banking, and securities laws relating to the provision of the advice. *See* section 408(g)(11)(A)(vi). As with affiliates, such an individual must, for purposes of section 408(g)(11)(A), not only be an employee, agent, or registered representative of one of those entities, but also must provide investment advice in his or her capacity as employee, agent, or registered representative. The Department, therefore, concluded that the language of section 408(g)(11)(A) required a finding that, for purposes of the statutory exemption, when an individual acts as an employee, agent or registered representative on behalf of an entity engaged to provide investment advice to a plan, that individual, as well as the entity, must be treated as the fiduciary adviser for purposes of section 408(g)(11)(A) and, accordingly subject to the limitations of section 408(g)(2)(A)(i). In an effort to accommodate a wider variety of business structures and practices, making investment advice more available while protecting participants and beneficiaries, the Department is proposing a class exemption addressing fee leveling requirements for employees, agents and registered representatives, also appearing in today's **Federal Register**.

In addition to the foregoing, fiduciary advisers utilizing investment advice arrangements that employ fee-leveling must comply with the requirements of paragraphs (e) [authorization by plan fiduciary], (f) [audits], (g) [disclosure], (h) [miscellaneous], and (i) [maintenance of records] of the proposal, each of which is discussed in more detail below.

3. Computer Models

Paragraph (d) of the proposal addresses the requirements applicable to investment advice arrangements that rely on computer models. In this regard, paragraph (d) provides, consistent with the provisions of section 408(g)(3)(B), (C) and (D), that an arrangement shall be an eligible investment advice arrangement if the only investment advice provided under the arrangement is advice that is generated by a computer model described in paragraphs (d)(1) and (2) of this section under an investment advice program, and with respect to which the requirements of paragraphs (e) [authorization by plan fiduciary], (f) [audits], (g) [disclosure], (h) [miscellaneous], and (i) [maintenance of records] of the proposal are met and any acquisition, holding or sale of a security or other property pursuant to such advice occurs solely at the direction of the participant or beneficiary.

Paragraph (d)(1), consistent with section 408(g)(3)(B)(i)–(v), sets forth the standards applicable to computer models. Specifically, paragraph (d)(1) requires that a computer model be designed and operated to: apply generally accepted investment theories that take into account the historic returns of different asset classes over defined periods of time, although nothing in the proposal is intended to preclude a computer model from applying generally accepted investment theories that take into account additional considerations; utilize information furnished by a participant or beneficiary relating to age, life expectancy, retirement age, risk tolerance, other assets or sources of income, and investment preferences, although nothing in the proposal precludes a computer model from taking into account additional information that a plan or a participant or beneficiary may provide; and utilize appropriate objective criteria to provide asset allocation portfolios comprised of investment options available under the plan. See paragraph (d)(1)(i)–(iii) of the proposal.

In addition to the foregoing, a computer model, consistent with section 408(g)(3)(B)(iv),[8] must be designed and operated to avoid investment recommendations that: inappropriately favor investment options offered by the fiduciary adviser or a person with a material affiliation or material contractual relationship with the fiduciary adviser over other investment options, if any, available under the plan; or inappropriately favor investment options that may generate greater income for the fiduciary adviser or a person with a material affiliation or material contractual relationship with the fiduciary adviser. In order to determine if further guidance can be developed with respect to this provision, the Department seeks public comment on circumstances under which it would be appropriate or inappropriate to favor particular investment options. For example, the Department believes that favoring a higher-cost investment alternative over an otherwise identical investment alternative with lower cost would be inappropriate.

As reflected in the language, a computer model would not fail to meet this requirement merely because the only investment options offered under the plan are options offered by the fiduciary adviser or a person with a material affiliation or material contractual relationship with the fiduciary adviser. The language also makes clear that models cannot be designed and operated to inappropriately favor those investment options that generate the most income for the fiduciary adviser or a person with a material affiliation or material contractual relationship with the fiduciary adviser. The proposal defines

[7] See AO 2005–10A; AO 97–15A.

[8] Pursuant to section 408(g)(3)(B)(iv), a computer model must operate ''in a manner that is not biased in favor of investments offered by the fiduciary adviser or a person with a material affiliation or contractual relationship with the fiduciary adviser.''

a ''material affiliation'' and ''material contractual relationship'' at paragraphs (j)(6) and (j)(7), respectively.

Paragraph (d)(1) further requires, consistent with section 408(g)(3)(B)(v),[9] that computer models take into account all ''designated investment options'' available under the plan without giving inappropriate weight to any investment option. See paragraph (d)(1)(v) of the proposal. The term ''designated investment option'' is defined in paragraph (j)(1) of the proposal, to mean any investment option designated by the plan into which participants and beneficiaries may direct the investment of assets held in, or contributed to, their individual accounts. The term ''designated investment option'' does not include ''brokerage windows,'' ''self-directed brokerage accounts,'' or similar plan arrangements that enable participants and beneficiaries to select investments beyond those designated by the plan.

Paragraph (d)(1)(v) also provides that a computer model shall not be treated as failing to take all designated investment options into account merely because it does not take into account an investment option that constitutes an investment primarily in qualifying employer securities. Any such limitation on the investment advice to be generated by the computer model, however, must be disclosed to participants and beneficiaries under paragraph (g)(1)(vi) of the proposal, discussed below. Information received by the Department in response to both of its RFIs indicated that there are challenges attendant to developing computer models, which generally are based on underlying theories that rely on diversified asset classes, that address a single undiversified security, such as qualifying employer securities, in connection with generating investment recommendations that would enable a participant to construct a well-diversified investment portfolio. The Department is concerned that extending this requirement to qualifying employer securities might discourage arrangements based on utilization of a computer model, or otherwise limit their availability.[10] Accordingly, the Department has excluded investments primarily in qualifying employer securities from the requirement of paragraph (d)(1)(v) of the proposal.

Paragraph (d)(2) of the proposal requires that, prior to utilization of the computer model, the fiduciary adviser obtain a written certification that the computer model meets the requirements of paragraph (d)(1), discussed above. If the model is modified in a manner that may affect its ability to meet the requirements of paragraph (d)(1), the fiduciary adviser, prior to utilization of the modified model, must obtain a new certification. With regard to the certification, paragraph (d)(2) requires that the fiduciary adviser obtain a certification that meets the requirements of paragraph (d)(4) from an ''eligible investment expert,'' within the meaning of paragraph (d)(3).

Paragraph (d)(3) of the proposal defines an ''eligible investment expert'' to mean a person that, through employees or otherwise, has the appropriate technical training or experience and proficiency to analyze, determine and certify, in a manner consistent with paragraph (d)(4), whether a computer model meets the requirements of paragraph (d)(1) of this section; except that the term eligible investment expert does not include any person that has any material affiliation or material contractual relationship with the fiduciary adviser, with a person with a material affiliation or material contractual relationship with the fiduciary adviser, or with any employee, agent, or registered representative of the foregoing. After consideration of the public comments, the Department has concluded that it would be very difficult to define a specific set of academic or other credentials that would serve to define the appropriate expertise and experience for an eligible investment expert.

Accordingly, under the proposal, it is the fiduciary adviser who is responsible for determining whether an eligible investment expert, itself or its employees, possesses the requisite training and experience to certify whether a given computer model meets the requirements of paragraph (d)(1) in a manner consistent with paragraph (d)(4) of the proposal. Paragraph (d)(5) of the proposal provides that, for purposes of the statutory exemption, the selection of the eligible investment expert by the fiduciary adviser is a fiduciary act governed by section 404(a)(1) of ERISA.

The Department notes that, although the proposal gives latitude to a fiduciary adviser in selecting an eligible investment expert to certify a computer model, as the party seeking prohibited transaction relief under the exemption, the fiduciary adviser has the burden of demonstrating that all applicable requirements of exemption are satisfied with respect to its arrangement. We also note that section 404 of ERISA requires the fiduciary adviser to act reasonably and prudently in its selection.

Paragraph (d)(4) of the proposal provides that a certification by an eligible investment expert shall be in writing and contain the following: an identification of the methodology or methodologies applied in determining whether the computer model meets the requirements of paragraph (d)(1) of this section; an explanation of how the applied methodology or methodologies demonstrated that the computer model met the requirements of paragraph (d)(1) of this section; and a description of any limitations that were imposed by any person on the eligible investment expert's selection or application of methodologies for determining whether the computer model meets the requirements of paragraph (d)(1). In addition the certification is required to contain a representation that the methodology or methodologies were applied by a person or persons with the educational background, technical training or experience necessary to analyze and determine whether the computer model meets the requirements of paragraph (d)(1); and a statement certifying that the eligible investment expert has determined that the computer model meets the requirements of paragraph (d)(1). Finally the certification must be signed by the eligible investment expert.

With regard to the certification described in paragraph (d)(4) of the proposal, public comments suggested a number of different approaches that could be followed in determining computer model consistency with the statutory criteria. The comments did not, however, suggest a single suitable approach. The Department, therefore, is wary of mandating a methodology under the proposal. The Department also believes that as computer models and their use under investment advice arrangements continue to develop, experts may need the flexibility to develop new methodologies for examining those models. Accordingly, paragraph (d)(4) does not require a particular methodology to be applied for purposes of certification.

[9] Section 408(g)(3)(B)(v) provides that computer models must take ''into account all investment options under the plan in specifying how a participant's account balance should be invested and is not inappropriately weighted with respect to any investment option.''

[10] It should be noted that, even in the absence of individualized advice, participants are reminded on a quarterly basis, via their pension benefit statements, of the importance of maintaining a diversified portfolio. Model language for purposes of this disclosure was set forth in Field Assistance Bulletin 2006–03 (Dec. 20, 2006). Among other things the model language provides that ''[I]f you invest more than 20% of your retirement savings in any one company or industry, your savings may not be properly diversified. Although diversification is not a guarantee against loss, it is an effective strategy to help you manage investment risk.''

4. Authorized by a Plan Fiduciary

Consistent with the section 408(g)(4) of ERISA, the proposal provides, at paragraph (e), that the arrangement pursuant to which investment advice is provided to participants and beneficiaries must be expressly authorized by a plan fiduciary (or, in the case of an IRA, the IRA beneficiary) other than: the person offering the arrangement; any person providing designated investment options under the plan; or any affiliate of either. The proposal further provides that for purposes of such authorization, an IRA beneficiary will not be treated as an affiliate of a person solely by reason of being an employee of such person, thereby enabling employees of a fiduciary adviser to take advantage of investment advice arrangements offered by their employer under the exemption.

5. Annual Audit

Paragraph (f) addresses the audit requirements of section 408(g)(6) of ERISA. Specifically, paragraph (f)(1) provides that the fiduciary adviser shall, at least annually, engage an independent auditor, who has appropriate technical training or experience and proficiency, and so represents in writing to the fiduciary adviser, to conduct an audit of the investment advice arrangements for compliance with the requirements of the proposal and within 60 days following completion of the audit, issue a written report to the fiduciary adviser and, except with respect to an arrangement with an IRA, to each fiduciary who authorized the use of the investment advice arrangement, consistent with paragraph (e) of the proposal, setting forth the specific findings of the auditor regarding compliance of the arrangement with the requirements of the proposal.

Given the significant number of reports that an auditor would be required to send if the written report was required to be furnished to all IRA beneficiaries, the Department framed an alternative requirement for investment advice arrangements for IRAs. This alternative is set forth in paragraph (f)(2) of the proposal. The alternative provides that, with respect to an arrangements with an IRA, the fiduciary adviser shall, within 30 days following receipt of the report from the auditor, furnish a copy of the report to the IRA beneficiary or make such report available on its website, provided that such beneficiaries are provided information, along with other required disclosures (see paragraph (g) of the proposal), concerning the purpose of the report, and how and where to locate the report applicable to their account. With respect to making the report available on a website, the Department believes that this alternative to furnishing reports to IRA beneficiaries satisfies the requirement of section 104(d)(1) of the Electronic Signatures in Global and National Commerce Act (E–SIGN) [11] that any exemption from the consumer consent requirements of section 101(c) of E–SIGN must be necessary to eliminate a substantial burden on electronic commerce and will not increase the material risk of harm to consumers. The Department solicits comments on this finding. Paragraph (f)(2) also provides that, when the report of the auditor identifies noncompliance with the requirements of the regulation, the fiduciary adviser must send a copy of the report to the Department. As proposed, the fiduciary adviser must submit the report to the Department within 30 days following receipt of the report from the auditor. The submission of this report will enable the Department to monitor compliance with the statutory exemption in those instances where there is no authorizing ERISA plan fiduciary to carry out that function.

For purposes of paragraph (f) of the proposal, an auditor is considered independent if it does not have a material affiliation or material contractual relationship with the person offering the investment advice arrangement to the plan or any designated investment options under the plan. The terms ''material affiliation'' and ''material contractual relationship'' are defined in paragraphs (j)(6) and (7) of the proposal.

With regard to the scope of the audit, paragraph (f)(4) provides that the auditor shall review sufficient relevant information to formulate an opinion as to whether the investment advice arrangements, and the advice provided pursuant thereto, offered by the fiduciary adviser during the audit period were in compliance with the regulation. Paragraph (f)(4) further provides that it is not intended to preclude an auditor from using information obtained by sampling, as reasonably determined appropriate by the auditor, investment advice arrangements, and the advice pursuant thereto, during the audit period. The proposal, therefore, does not require an audit of every investment advice arrangement at the plan or fiduciary adviser-level or of all the advice that is provided under the exemption. In general, the proposal leaves to the auditor the determination as to the appropriate scope of their review and the extent to which they can rely on representative samples for determining compliance with the exemption.

6. Disclosure

The disclosure provisions are set forth in paragraph (g) of the proposal and generally track the disclosure provisions of the statutory exemption at section 408(g)(6) of ERISA. In this regard, the proposal, at paragraph (g)(1), requires that the fiduciary adviser provide to participants and beneficiaries, prior to the initial provision of investment advice with regard to any security or other property offered as an investment option, a written notification describing: the role of any party that has a material affiliation or material contractual relationship with the fiduciary adviser in the development of the investment advice program, and in the selection of investment options available under the plan; the past performance and historical rates of return of the designated investment options available under the plan, to the extent that such information is not otherwise provided; all fees or other compensation relating to the advice that the fiduciary adviser or any affiliate thereof is to receive (including compensation provided by any third party) in connection with the provision of the advice or in connection with the sale, acquisition, or holding of the security or other property; and any material affiliation or material contractual relationship of the fiduciary adviser or affiliates thereof in the security or other property.

The notification to participants and beneficiaries also is required to explain: the manner, and under what circumstances, any participant or beneficiary information provided under the arrangement will be used or disclosed; the types of services provided by the fiduciary adviser in connection with the provision of investment advice by the fiduciary adviser, including, with respect to an arrangement described in paragraph (d) utilizing a computer model, any limitations on the ability of the model to take into account an investment primarily in qualifying employer securities, as provided for in paragraph (d)(1)(v) of the proposal; that the adviser is acting as a fiduciary of the plan in connection with the provision of the advice; and that a recipient of the advice may separately arrange for the provision of advice by another adviser that could have no material affiliation with and receive no fees or other compensation in connection with the security or other property.

[11] 15 U.S.C. 7004(d)(1) (2000).

Paragraph (g)(2) of the proposal requires that the notification furnished to participants and beneficiaries be written in a clear and conspicuous manner and in a manner calculated to be understood by the average plan participant and must be sufficiently accurate and comprehensive to reasonably apprise such participants and beneficiaries of the information required to be provided in the notification.

The appendix to the proposal contains a model disclosure form that may be used for purposes of satisfying the fee and compensation disclosure requirement of paragraph (g)(1)(iii), as well as the requirements of paragraph (g)(2), of the proposal. The proposal makes clear, however, that the use of the model disclosure form is not mandatory.

Paragraph (g)(3) makes clear that the required disclosures may be provided in written or electronic form.

Paragraph (g)(4) of the proposal, like section 408(g)(6)(B) of ERISA, sets forth miscellaneous recordkeeping and furnishing responsibilities of the fiduciary adviser. Specifically, paragraph (g)(4) provides that, at all times during the provision of advisory services to the participant or beneficiary pursuant to the arrangement, the fiduciary adviser must: Maintain the information described in paragraph (g)(1) in accurate form; provide, without charge, accurate information to the recipient of the advice no less frequently than annually; provide, without charge, accurate information to the recipient of the advice upon request of the recipient; and provide, without charge, accurate information to the recipient of the advice concerning any material change to the information required to be provided to the recipient of the advice at a time reasonably contemporaneous to the change in information.

7. Other Conditions

Paragraph (h) of the proposal, like section 408(g)(7) of ERISA, sets forth additional conditions applicable to the provision of advice under the statutory exemption. These requirements are as follows: The fiduciary adviser must provide appropriate disclosure, in connection with the sale, acquisition, or holding of the security or other property, in accordance with all applicable securities laws; the sale, acquisition, or holding occurs solely at the direction of the recipient of the advice; the compensation received by the fiduciary adviser and affiliates thereof in connection with the sale, acquisition, or holding of the security or other property is reasonable; and the terms of the sale, acquisition, or holding of the security or other property are at least as favorable to the plan as an arm's length transaction would be.

8. Maintenance of Records

Paragraph (i) of the proposal sets forth the record maintenance requirements. Consistent with section 408(g)(9) of ERISA, paragraph (i) of the proposal provides that the fiduciary adviser must maintain, for a period of not less than 6 years after the provision of investment advice pursuant to the arrangement, any records necessary for determining whether the applicable requirements of the proposal have been met. Also, paragraph (i), as with section 408(g)(9), makes clear that a prohibited transaction shall not be considered to have occurred solely because the records are lost or destroyed prior to the end of the 6-year period due to circumstances beyond the control of the fiduciary adviser.

9. Definitions

Paragraph (j) of the proposal sets forth a number of definitions relevant to the statutory exemption and this proposed regulation.

Paragraph (j)(1), as discussed earlier, defines the term ''designated investment option.'' Paragraph (j)(2) sets forth the definition of ''fiduciary adviser,'' as it appears in section 408(g)(11)(A) of ERISA. With regard to that part of the fiduciary adviser definition that treats persons who develop computer models or market investment advice programs or computer models as a fiduciary of the plan by reason of providing investment advice and as a fiduciary adviser for purposes of section 408(b)(14), the Department is proposing a separate regulation (§ 2550.408g–2), discussed below, pursuant to which a single fiduciary adviser may elect to be treated as a fiduciary with the respect to the plan.

Paragraph (j)(3) of the proposal adopts the statutory definition of ''registered representative'' set forth in ERISA section 408(g)(11)(C), which states that a registered representative of another entity means a person described in section 3(a)(18) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(18)) (substituting the entity for the broker or dealer referred to in such section) or a person described in section 202(a)(17) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–2(a)(17)) (substituting the entity for the investment adviser referred to in such section).

Paragraph (j)(4), consistent with section 601(b)(3)(A)(i) of the Pension Protection Act of 2006, defines the term ''Individual Retirement Account'' to mean plans described in paragraphs (B) through (F) of section 4975(e)(1) of the Code, as well as a trust, plan, account, or annuity which, at any time, has been determined by the Secretary of the Treasury to be described in such paragraphs.

Paragraph (j)(5) of the proposed rule defines the term ''affiliate.'' For purposes of the proposal, an ''affiliate'' of another person means: Any person directly or indirectly owning, controlling, or holding with power to vote, 5 percent or more of the outstanding voting securities of such other person; any person 5 percent or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such other person; any person directly or indirectly controlling, controlled by, or under common control with, such other person; and any officer, director, partner, copartner, or employee of such other person. Consistent with ERISA section 408(g)(11)(B), this definition is based on the definition of an ''affiliated person'' of an entity as contained in section 2(a)(3) of the Investment Company Act of 1940 (ICA), except that it does not reflect clauses (E) and (F) thereof. The Department has initially determined that including provisions similar to clauses (E) and (F) is unnecessary, because these clauses appear to focus on persons who exercise control over the management of an investment company.[12] Also, such parties will nonetheless be treated as an affiliate because they would be a person directly or indirectly controlling, controlled by, or under common control with, such other person. See paragraph (j)(5)(iii) of the proposal. Additionally, the Department is concerned that including provisions similar to clauses (E) and (F), which focus on functions involving investment companies, but not other types of vehicles in which plans may invest, could have the unintended consequence of possibly subjecting persons associated with investment companies to different requirements under these proposed regulations. Therefore, the Department is proposing to define affiliate without regard to clauses (E) and (F) of section 2(a)(3) of the ICA.

In a variety of places in the regulation reference is made to persons with

[12] ICA section 2(a)(3)(E) and (F) include in the definition of affiliated person: If the other person is an investment company, any investment adviser thereof or any member of an advisory board thereof; and if such other person is an unincorporated investment company not having a board of directors, the depositor thereof. 15 U.S.C. 80a–2(a)(3)(E)–(F).

''material affiliations'' and ''material contractual relationships.'' See paragraphs (d)(1)(iv), (d)(3), (f)(3), (g)(1)(i), (g)(1)(iv) and (g)(1)(viii) of the proposal. For purposes of this regulation, those terms are defined in paragraphs (j)(6) and (j)(7), respectively.

Paragraph (j)(6) of the proposal describes a person with a ''material affiliation'' with another person as: Any affiliate of such other person; any person directly or indirectly owning, controlling, or holding, 5 percent or more of the interests of such other person; or any person 5 percent or more of whose interests are directly or indirectly owned, controlled, or held, by such other person. In determining ''interest,'' paragraph (j)(6)(ii) provides that an ''interest'' means with respect to an entity: The combined voting power of all classes of stock entitled to vote or the total value of the shares of all classes of stock of the entity if the entity is a corporation; the capital interest or the profits interest of the entity if the entity is a partnership; or the beneficial interest of the entity if the entity is a trust or unincorporated enterprise.

Paragraph (j)(7) of the proposal provides that persons shall be treated as having a ''material contractual relationship'' if payments made by one person to the other person pursuant to written contracts or agreements between the persons exceed 10 percent of the gross revenue, on an annual basis, of such other person. The Department believes that one person's receipt of more than 10 percent of gross revenue from another person is sufficiently significant to be considered material. However, the Department specifically invites comments on whether the percentage test should be higher or lower and, if so, why.

The proposal, at paragraph (j)(8), defines ''control'' to mean the power to exercise a controlling influence over the management or policies of a person other than an individual.

C. Overview of Proposed § 2550.408g–2

Proposed § 2550.408g–2, as indicated above, addresses the requirements for electing to be treated as a fiduciary and fiduciary adviser by reason of developing or marketing a computer model or an investment advice program used in an eligible investment advice arrangement. See section 408(g)(11)(A).

Section 408(g)(11)(A) provides that, with respect to an arrangement that relies on use of a computer model to qualify as an ''eligible investment advice arrangement,'' a person who develops the computer model, or markets the investment advice program or computer model, shall be treated as a fiduciary of a plan by reason of the provision of investment advice referred to in ERISA section 3(21)(A)(ii) to the plan participant or beneficiary, and shall be treated as a ''fiduciary adviser'' for purposes of ERISA section 408(b)(14) and (g). Section 4975(f)(8) of the Code contains a parallel provision to ERISA section 408(g)(11)(A). Proposed § 2550.408g–2 sets forth requirements that must be satisfied in order for one such fiduciary adviser to elect to be treated as a fiduciary under such an eligible investment advice arrangement. See paragraph (a) of § 2550.408g–2.

Paragraph (b)(1) of § 2550.408g–2 provides that if an election meets the requirements of paragraph (b)(2) of the proposal, then the person identified in the election shall be the sole fiduciary adviser treated as a fiduciary by reason of developing or marketing a computer model, or marketing an investment advice program, used in an eligible investment advice arrangement. Paragraph (b)(2) requires that the election be in writing and that the writing: Identify the arrangement, and person offering the arrangement, with respect to which the election is to be effective; and identify the person who is the fiduciary adviser, the person who develops the computer model or markets the computer model or investment advice program with respect to the arrangement, and the person who elects to be treated as the only fiduciary, and fiduciary adviser, by reason of developing such computer model or marketing such computer model or investment advice program. Paragraph (b)(2) of § 2550.408g–2 also requires that the election be signed by the person acknowledging that it elects to be treated as the only fiduciary and fiduciary adviser; that a copy of the election be furnished to the plan fiduciary who authorized use of the arrangement; and that the writing be retained in accordance with the record retention requirements of § 2550.408g–1(i).

D. Effective Date

The Department proposes that the regulations contained in this notice will be effective 60 days after publication of the final regulations in the **Federal Register**. The Department invites comments on whether the final regulations should be made effective on a different date.

E. Request for Comments

The Department invites comments from interested persons on the proposed regulations. To facilitate the receipt and processing of comment letters, the Employee Benefits Security Administration (EBSA) encourages interested persons to submit their comments electronically by e-mail to *e-ORI@dol.gov* (Subject: Investment Advice Regulations), or by using the Federal eRulemaking portal at *http://www.regulations.gov* (follow instructions for submission of comments). Persons submitting comments electronically are encouraged not to submit paper copies. Persons interested in submitting paper copies should send or deliver their comments to the Office of Regulations and Interpretations, Employee Benefits Security Administration, Attn: Investment Advice Regulations, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. All comments will be available to the public, without charge, online at *http://www.regulations.gov and http://www.dol.gov/ebsa* and at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

The comment period for the proposed regulations will end 45 days after publication of the proposed rule in the **Federal Register**. The Department believes that this period of time will afford interested persons an adequate amount of time to analyze the proposals and submit comments. Written comments on the proposed regulations should be submitted to the Department of Labor on or before October 6, 2008.

F. Regulatory Impact Analysis

Summary

The Department anticipates that this proposed regulation and proposed class exemption, by extending quality, expert investment advice to more retirement plan participants, together will improve their investment results by approximately $14 billion or more annually, at a cost of $4 billion, thereby producing a net financial benefit of $10 billion or more. The improved investment results will reflect reductions in investment errors such as payment of higher than necessary fees and expenses, poor trading strategies, and inadequate diversification. The provisions of this proposed regulation and the conditions attached to this proposed class exemption reflect the Department's efforts to ensure that the advice provided pursuant to them will be affordable and of high quality.

Introduction

Workers' retirement security increasingly depends on their investment decisions. Unfortunately

there is evidence that many participants and beneficiaries in participant-directed defined contribution (DC) plans and beneficiaries of individual retirement accounts (IRAs) (collectively hereafter, ''participants''), beset by flawed information or reasoning, make poor investment decisions. These participants may pay higher fees and expenses than necessary for investment products and services, engage in excessive or poorly timed trading or fail to rebalance their portfolios, inadequately diversify their portfolios and thereby assume uncompensated risk, take more or less than optimal levels of compensated risk, and/or pay unnecessarily high taxes. Financial losses (including foregone earnings) from such mistakes likely amount to more than $100 billion per year. These losses compound and grow larger as workers progress toward and into retirement.

Such mistakes and consequent losses historically can be attributed at least in part to provisions of federal law that effectively preclude a variety of arrangements whereby financial professionals might otherwise provide retirement plan participants with expert investment advice. These ''prohibited transaction'' provisions of ERISA and the Internal Revenue Code prohibit fiduciaries from dealing with DC plan or IRA assets in ways that advance their own interests. These provisions prohibit plan fiduciaries from exercising the authority, control, or responsibility that makes such persons fiduciaries when they have an interest which may conflict with the interests of the plan for which they act. Under these provisions financial advisers who have a direct or indirect stake in participants' investment decisions generally may not provide them with investment advice. In recognition that certain transactions could nonetheless be beneficial to plans and their participants and beneficiaries, subject to safeguards appropriate to protect against potential abuses, Congress enacted a number of statutory prohibited transaction exemptions, and also gave the Department conditional authority to grant prohibited transaction exemptions. In this regard, the prohibited transaction exemption for the provision of investment advice added by the Pension Protection Act of 2006 (PPA) opened the door to more types of investment advice arrangements by conditionally permitting arrangements where the fiduciary adviser or an affiliate thereof has a financial stake in the advised participants' investment decisions. The Department is proposing a regulation to further specify the PPA's applicable conditions, together with a class exemption to establish alternative conditions under which such arrangements may operate. Together these actions are intended to increase the availability of investment advice.

The results of this proposed regulation and proposed class exemption will depend on their impacts on the availability, cost, use, and quality of participant investment advice. The Department expects that, as a result of these actions, quality, affordable advice will proliferate, producing significant net gains for participants.

Investment Mistakes

The Department believes that many participants make costly investment mistakes and therefore could benefit from receiving and following good advice. In theory, investors can optimize their investment mix over time to match their investment horizon and personal taste for risk and return. But in practice many investors do not optimize their investments, at least not in accordance with generally accepted financial theories.

Some investors fail to exhibit clear, fixed and rational preferences for risk and return. Some base their decisions on flawed information or reasoning. For example some appear to anchor decisions inappropriately to plan features or to mental accounts or frames, or to rely excessively on past performance measures or peer examples. Some suffer from overconfidence, myopia, or simple inertia.[13]

Such informational and behavioral problems translate into at least five distinct types of investment mistakes,[14] which together generate financial losses (including foregone earnings) of $109 billion or more annually [15] for DC plan and IRA participants, the Department estimates.

Fees and Expenses

Investors sometimes pay higher fees and expenses than necessary for investment products and services. There is evidence that mutual funds with poorer gross performance (that is performance before deducting fees) also have higher fees. This suggests that higher fees sometimes do not reflect value added by managers. Investors often pay inadequate attention to fee differences, even in connection with highly comparable products like competing S&P 500 index funds.[16]

[13] See, *e.g.*, Richard H. Thaler & Shlomo Benartzi, *The Behavioral Economics of Retirement Savings Behavior,* AARP Public Policy Institute White Paper 2007–02 (Jan. 2007); and Jeffrey R. Brown & Scott Weisbenner, *Individual Account Investment Options and Portfolio Choice: Behavioral Lessons from 401(k) Plans,* Social Science Research Network Abstract 631886 (Dec. 2004).

[14] It should be noted that much of the research documenting investment mistakes does not account for whether advice was present or not. At least some of the mistakes may have been made despite good advice to the contrary; some may have been made pursuant to bad advice. There is evidence both that advice sometimes is not followed, and that it sometimes is bad. This is explored more below.

[15] As discussed below, this estimate is subject to wide uncertainty.

[16] A number of studies conclude that investors often pay higher fees than necessary.

Javier Gil-Bazo & Pablo Ruiz-Verdú, *Yet Another Puzzle? Relation Between Price and Performance in the Mutual Fund Industry,* Social Science Research Network Abstract 947448 (March 2007) find that funds with worse before-fee performance charge higher fees. They suggest that funds faced with insensitive investors charge higher fees, finding that even after controlling for performance sensitivity, funds with lower expected performance set higher fees. They hypothesize that lower performing funds lose sophisticated investors to higher performing funds, then are left with relatively unsophisticated investors who are not as responsive to price.

According to Ali Hortacsu & Chad Syverson, *Product Differentiation, Search Costs, and Competition in the Mutual Fund Industry: A Case Study of S&P 500 Index Funds,* Social Science Research Network Abstract 405642 (April 2003), 75 percent of S&P 500 Index Funds have expense ratios in excess of 47 basis points, 50 percent in excess of 72 basis points and 25 percent in excess of 149 basis points. The highest cost fund charged annualized investor fees that were nearly 30 times greater than the lowest-cost fund (268 vs. 9.5 basis points). Low-cost funds have a dominant market share, but the asset share of the low-cost funds has fallen consistently since 1995.

Paul G. Mahoney, *Manager-Investor Conflicts in Mutual Funds,* The Journal of Economic Perspectives, Volume 18, Number 2 (2004) extends the Ali Hortacsu & Chad Syverson, *Product Differentiation, Search Costs, and Competition in the Mutual Fund Industry: A Case Study of S&P 500 Index Funds,* Social Science Research Network Abstract 405642 (April 2003) result of two classes of investors, the experienced that buy low-cost no-load funds, and the novice who uses a broker and buys high-cost load funds. He finds that, even after separating the expense ratio into administrative fees and 12b–1 fees, funds with loads still have administrative fees 15 basis point higher than the no-load funds.

Brad M. Barber *et al., Out of Sight, Out of Mind, The Effects of Expenses on Mutual Fund Flows,* Journal of Business, Volume 79, Number 6 2095, 2095–2119 (2005) find that investors are sensitive to load fees. They argue that front-end load fees are generally observable as a dollar amount on the first statement while the effects of administrative fees on the account balance are hidden by the volatility of fund returns. They find evidence of learning; repeat mutual fund purchasers pay on average about half the load fees of first time mutual fund purchasers.

Todd Houge & Jay W. Wellman, *The Use and Abuse of Mutual Fund Expenses,* Social Science Research Network Abstract 880463 (Jan. 2006) present evidence that less knowledgable investors pay consistently higher asset management fees than more knowledgable investors holding similar funds. Less sophisticated investors are more likely to invest in funds with loads. Load funds on average have annual expense ratios that are 50 basis points higher than no-load funds. While a large part of the higher expense ratio is composed of 12b–1 fees, load funds also have higher asset management fees. They conclude that ''Load fund shareholders often pay high fees to market and grow the fund, but the

Continued

The Department estimates that DC plan participants [17] and IRA beneficiaries together recently paid fees and expenses that were higher than necessary by $8 billion or more annually on aggregate.[18] Good advice could eliminate some of this unnecessary expense.[19]

Poor Trading Strategies

There is evidence that some participants trade excessively, while many more trade too little, failing even to rebalance. In DC plans, participant trading often worsens performance, and those with automatic rebalancing generally fare best.[20] Relative to automatic rebalancing, inferior trading strategies recently cost participants perhaps $56 billion or more annually, the Department estimates.[21] Among inferior strategies, it is likely that active trading aimed at timing the market generates more adverse results than failing to rebalance. Many mutual funds investors' experience badly lags the performance of the funds they hold because they buy and sell shares too frequently and/or at the wrong times.[22] Investors often buy and sell in response to short-term past returns, and suffer as a result.[23] Good advice is likely to discourage market timing efforts and encourage rebalancing, thereby ameliorating adverse impacts from poor trading strategies.

Inadequate Diversification

Investors sometimes fail to diversify adequately and thereby assume uncompensated risk and suffer associated losses. For example, DC plan participants sometimes concentrate their assets excessively in stock of their employer.[24] Relative to full diversification,[25] employer stock investments recently cost DC plan participants perhaps $3 billion [26] annually, the Department estimates.[27] Other lapses in diversification may involve omission from portfolios of

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fund's advisor is the most likely beneficiary of this growth.''

Edwin J. Elton *et al., Are Investors Rational? Choices Among Index Funds,* Social Science Research Network Abstract 340482 (June 2002) find that buying S&P 500 index mutual funds using expenses as the predictor of future success leads to picking funds with better returns. They find that the ten percent of funds with the lowest expenses out performs the ten percent of funds with the highest expenses by 0.92 percent a year. They find that for S&P 500 index mutual funds, the incentive for brokers and financial planners to push the fund (as represented by loads) is more important for new flows than is avoiding high cost and poorly performing funds. They are unable to find any effect of the quality of services on flows.

James J. Choi *et al., Why Does the Law of One Price Fail? An Experiment on Index Mutual Funds,* National Bureau of Economic Research Working Paper W12261 (May 2006) offer experimental evidence that index fund investors are largely insensitive to fees.

Some other studies suggest, however, that fee levels may in fact be competitive and efficient. Many studies fail to measure potential non-financial benefits investors might derive from professional investment advice. Victoria Leonard-Chambers & Michael Bogdan, *Why Do Mutual Fund Investors Use Professional Financial Advisers?,* Investment Company Institute Research Fundamentals, Volume 16, Number 1 (April 2007) present results of a survey ''that identifies the benefits investors say they receive from using professional financial advisers,'' and contrast this perspective with that of studies that rely on ''performance and other publicly available measures to examine the value'' of such advice. Other studies find that investors with more intelligence or financial literacy often pay similar fees as those with less, and suggest this is consistent with the hypothesis that fees are competitive and efficient (see, *e.g.*, Sebastian Miller & Martin Weber, *Financial Literacy and Mutual Fund Investments: Who Buys Actively Managed Funds?,* Social Science Research Network Abstract 1093305 (Feb. 2008); and Mark Grinblatt *et al., Are Mutual Fund Fees Competitive? What IQ-Related Behavior Tells Us,* Social Science Research Network Abstract 1087120 (Nov. 2007)).

The Department understands that some of what might otherwise appear to be higher than necessary fees paid by investors pursuant to advice may in fact reflect indirect payment of the reasonable cost of the advice itself.

[17] DC plan participants' investment choices typically are limited to a menu selected by a plan fiduciary who is responsible for ensuring that the associated fees and expenses are reasonable. However, such participants may pay more overall than would be optimal if they do not appropriately consider fees and expenses when allocating their assets across available investments.

[18] ''Higher than necessary'' here means that the participant could have obtained equal value without incurring the expense. This calculation assumes that participants on average pay 11 or more basis points in unnecessary fees and expenses, in the form of expense ratios or loads. This assumption is likely to be conservative in light of evidence on the distribution of investor expense levels presented in Deloitte Financial Advisory Services LLP, *Fees and Revenue Sharing in Defined Contribution Retirement Plans* (Dec. 6, 2007) (unpublished, on file with the Department of Labor); Brad M. Barber *et al., Out of Sight, Out of Mind, The Effects of Expenses on Mutual Fund Flows,* Journal of Business, Volume 79, Number 6 2095, 2095–2119 (2005); Edwin J. Elton *et al., Are Investors Rational? Choices Among Index Funds,* Social Science Research Network Abstract 340482 (June 2002); James J. Choi *et al., Why Does the Law of One Price Fail? An Experiment on Index Mutual Funds,* National Bureau of Economic Research Working Paper W12261 (May 2006); and Sarah Holden & Michael Hadley, *The Economics of Providing 401(k) Plans: Services, Fees and Expenses 2006,* Investment Company Institute Research Fundamentals, Volume 16, Number 4 (Sept. 2007). This estimate of excess expense does not take into account less visible expenses such as mutual funds' internal transaction costs (including explicit brokerage commissions and implicit trading costs), which are sometimes larger than funds' expense ratios (Deloitte Financial Advisory Services LLP, *Fees and Revenue Sharing in Defined Contribution Retirement Plans* (Dec. 6, 2007) (unpublished, on file with the Department of Labor); Jason Karceski *et al., Portfolio Transactions Costs at U.S. Equity Mutual Funds,* University of Florida Working Paper (2004), at *http://thefloat.typepad.com/the_float/files/2004_zag_study_on_mutual_fund_trading_costs.pdf).*

[19] Conversely, there is evidence that some higher than necessary expense currently is a direct result of what might be called bad advice, meaning certain marketing activities carried out by intermediaries such as brokers as well as direct consumer advertising by vendors of funds and competing financial products.

[20] See, *e.g.*, Takeshi Yamaguchi *et al., Winners and Losers: 401(k) Trading and Portfolio Performance,* Michigan Retirement Research Center Working Paper WP2007–154 (June 2007).

[21] This estimate is derived from the risk adjusted returns attributed to participants with different trading strategies, see id.

[22] See, *e.g.*, Dalbar Inc., *Quantitative Analysis of Investor Behavior 2007* (2007).

[23] See, *e.g.*, Rene Fischer & Ralf Gerhardt, *Investment Mistakes of Individual Investors and the Impact of Financial Advice,* Science Research Network Abstract 1009196 (Aug. 2007); Julie Agnew & Pierluigi Balduzzi, *Transfer Activity in 401(k) Plans,* Social Science Research Network Abstract 342600 (June 2006); and George Cashman *et al., Investor Behavior in the Mutual Fund Industry: Evidence from Gross Flows,* Social Science Research Network Abstract 966360 (Feb. 2007).

[24] See, *e.g.*, Olivia S. Mitchell & Stephen P. Utkus, *The Role of Company Stock in Defined Contribution Plans,* National Bureau of Economic Research Working Paper W9250 (Oct. 2002); and Jeffrey R. Brown & Scott Weisbenner, *Individual Account Investment Options and Portfolio Choice: Behavioral Lessons from 401(k) Plans,* Social Science Research Network Abstract 631886 (Dec. 2004).

[25] This comparison should be viewed as an outer bound. Full diversification of the same assets might not be feasible if companies are unwilling to alter the compensation mix in this way (see, *e.g.*, Olivia S. Mitchell & Stephen P. Utkus, *The Role of Company Stock in Defined Contribution Plans,* National Bureau of Economic Research Working Paper W9250 (Oct. 2002)). It also neglects some potential tax benefits of employer stock investments that might offset losses from reduced diversification (see, *e.g.*, Mukesh Bajaj *et al., The NUA Benefit and Optimal Investment in Company Stock in 401(k) Accounts,* Social Science Research Network Abstract 965808 (Feb. 2007)).

[26] Following findings reported in Lisa K. Meulbroek, *Company Stock in Pension Plans: How Costly Is It?,* Social Science Research Network Abstract 303782 (Mar. 2002), this estimate reflects losses amounting to 14 percent of the employer stock's value, assuming 10 percent of DC plan assets are held in employer stock, the DC plan is one-half of total wealth, and the holding period is 10 years. For comparison, following findings reported in Krishna Ramaswamy, *Company Stock and Pension Plan Diversification, in The Pension Challenge: Risk Transfers and Retirement Income Security* 71, 71–88 (Olivia S. Mitchell & Kent Smetters eds., 2003), the annualized cost of an option to receive the higher of the return on a typical company stock or the return on a fully diversified equity portfolio over a three-year horizon would amount to approximately $24 billion, the Department estimates. This measure probably exaggerates the loss to participants, however, insofar as it would preserve for the participant the potential upside of a company stock that outperforms the market.

[27] These estimates neglect any behavioral impact full diversification might have on asset allocation. There is some evidence that investing in employer stock increases participants' exposure to equity overall, which might increase average wealth (see, *e.g.*, Jack L. Vanderhei, *The Role of Company Stock in 401(k) Plans,* Employee Benefit Research Institute T–133 Written Statement for the House Education and Workforce Committee, Subcommittee on Employer-Employee Relations, Hearing on Enron and Beyond: Enhancing Worker Retirement Security (Feb. 2002), *at http://www.ebri.org/pdf/publications/testimony/t133.pdf).*

asset classes such as overseas equity or debt, small cap stocks, or real estate. Such lapses may sometimes reflect limited investment menus supplied by DC plans.[28] Yet even where adequate choices are available and company stock is not a factor, investors sometimes fail to diversify adequately.[29] Inadequate diversification other than excessive concentration in company stock recently cost participants perhaps $42 billion annually, the Department estimates.[30] Good advice should address over concentration in employer stock and other failures to properly diversify.

Inappropriate Risk

Investors who avoid the foregoing three mistakes might be said to invest efficiently, in the sense that they generally can expect the maximum possible return given their level risk. However, they may still be making a costly mistake: they may fail to calibrate the risk and return of their portfolio to match their own risk and return preferences. As a result, their investments may be too risky or too safe for their own tastes. The Department lacks a basis on which to estimate the magnitude of such mistakes, but believes they may be common and large. A diversified portfolio's risk and return characteristics generally is determined by its allocation across asset classes. As noted above, there is ample evidence that participants' asset allocation choices often are inconsistent with fixed or well behaved risk and return preferences. If participants' true preferences are in fact fixed or well behaved, then observed asset allocations, which often appear to shift in response to seemingly irrelevant factors (or fail to shift in response to relevant ones), certainly entail large welfare losses.[31] Good advice might help participants calibrate their asset allocations to match their true preferences.

Excess Taxes

It is likely that many households pay excess taxes as a result of disconnects between their investment and tax strategies. Households saving for retirement must decide not only what assets to hold, but also whether to locate these assets in taxable or tax-deferred accounts. For example, households may be able to maximize their expected after-tax wealth by first placing heavily taxed bonds in their tax-deferred account and then placing lightly taxed equities in their taxable account. A significant number of households do not follow this practice, however. By one estimate, to fully implement this practice in 1998, U.S. households would have had to relocate some $251 billion in assets.[32] It is not clear, however, whether such households are in fact making investment mistakes. In practice, this simple asset location rule may fail to minimize taxes.[33] As a result the Department has no basis to estimate the magnitude of excess taxes that might derive from DC plan and IRA participants' investment mistakes. In any event it is unclear whether or to what extent investment advisers would be positioned to provide advice on tax efficiency.

Promoting Investment Advice

Permissible Arrangements

Federal law limits the variety of arrangements whereby participants may obtain investment advice. Specifically, ERISA and the Internal Revenue Code generally prohibit fiduciaries from dealing with DC plan or IRA assets in ways that advance their own interests. These provisions effectively preclude participants from obtaining advice under arrangements that are widely used by other investors. For example, under many common arrangements, the adviser may receive a commission or other consideration when the investor enters into a transaction pursuant to the advice. The adviser's employer or an affiliate thereof may receive a sales load or other consideration in connection with the transaction. Stated generally, many common investment advice arrangements present financial advisers with opportunities to self deal.

While generally prohibiting arrangements that present such opportunities, federal law also provides for conditional exemptions whereby otherwise prohibited transactions are permitted. Some exemptions are contained in the statute. The Department has authority to grant others. The conditions attached to such exemptions serve to mitigate the adverse effects of the conflicts of interest that are present and thereby protect participants' interests. However, the Department invites suggestions for other safeguards against conflicts of interest that would be consistent with the goal of making quality advice more widely available.

The Pension Protection Act of 2006 opened the door to more types of investment advice arrangements by conditionally permitting arrangements where the fiduciary adviser or an affiliate thereof has a financial stake in

[28] See, *e.g.*, Edwin J. Elton *et al., The Adequacy of Investment Choices Offered By 401(k) Plans,* Social Science Research Network Abstract 567122 (Mar. 2004), which finds that menus are frequently inadequate, and Ning Tang and Olivia S. Mitchell, *The Efficiency of Pension Plan Investment Menus: Investment Choices in Defined Contribution Pension Plans,* University of Michigan Retirement Research Center Working Paper WP 2008–176 (June 2008), *at http://www.mrrc.isr.umich.edu/publications/papers/pdf/wp176.pdf,* which finds that most menus are efficient.

[29] See, *e.g.*, Laurent E. Calvet *et al., Down or Out: Assessing the Welfare Costs of Household Investment Mistakes,* Harvard Institute of Economic Research Discussion Paper No. 2107 (Feb. 2006).

[30] See id. This estimate assumes annual return decrements from inadequate diversification of 0.3 percent of invested assets for investors that are already investing in risky assets (like stocks and mutual funds) and 3.3% for investors that are not yet investing in risky assets. The Department estimates that in the U.S. about 85% of investors include risky assets in their portfolios.

[31] The potential financial effects of changes in asset allocation hint at the likely magnitude of these welfare effects. The Department previously has estimated that movement of DC plan default investments from stand-alone, low-risk capital preservation instruments to diversified portfolios that include equities will improve investment results for a large majority of affected individuals, increasing aggregate account balances by an estimated $5 billion to $7 billion in 2034 (See 72 FR 60,452, 60,466 (Oct. 24, 2007)).

[32] See, *e.g.*, Daniel B. Bergstresser & James M. Poterba, *Asset Allocation and Asset Location: Household Evidence from the Survey of Consumer Finances,* Journal of Public Economics, Volume 88 1893, 1893–1915 (2004).

[33] For example, tax-exempt municipal bonds are available, and actively managed equity mutual funds are not always tax-efficient (see, *e.g.*, James M. Poterba *et al., Asset Location for Retirement Savers, in Public Policies and Private Pensions* 290, 290–331 (John B. Shoven *et al.* eds., 2004); and John B. Shoven & Clemens Sialm, *Asset Location in Tax-Deferred and Conventional Savings Accounts,* Journal of Public Economics, Volume 88 (2003)). Using historical returns data and tax rate data for the period 1962–98, James M. Poterba *et al., Asset Location for Retirement Savers, in Public Policies and Private Pensions* 290, 290–331 (John B. Shoven *et al.* eds., 2004) find that when investing in actively managed mutual funds, and with the availability of tax-exempt bonds, households would have more after-tax wealth in most cases if they had first placed equities in the tax-deferred account. Gene Amromin, *Portfolio Allocation Choices in Taxable and Tax-Deferred Accounts: An Empirical Analysis of Tax-Efficiency,* Social Science Research Network Abstract 302824 (May 2002) describes how accessibility restrictions on assets in tax-deferred retirement accounts create a tension between making tax-efficient placements and the risk of having to make costly withdrawals in the event of a bad labor income shock. He presents empirical evidence that holding apparently tax-inefficient portfolios is related to accessibility restrictions and to precautionary motives. Lorenzo Garlappi & Jennifer C. Huang, *Are Stocks Desirable in Tax-Deferred Accounts?,* Journal of Public Economics, Volume 90 2257, 2257–2283 (July 2006) explain how a tax-deferred account essentially confers a tax subsidy onto its holdings. While the level of the tax subsidy may be maximized by first placing bonds in the tax-deferred account, this strategy may lead to a more volatile tax benefit. Risk-averse households may wish to smooth this volatility by holding a mix of equities and bonds in both tax-deferred and taxable accounts, as some are observed to do in practice. Robert M. Dammon *et al., Optimal Asset Location and Allocation with Taxable and Tax-Deferred Investing,* The Journal of Finance, Volume LIX, Number 3 999, 999–1037 (2004) find that even when tax-exempt bonds are available and even when there are liquidity shocks, for most investors it is best to put taxable bonds in the tax-deferred account and equity in the taxable account.

the advised participants' investment decisions. The Department is proposing a regulation to further specify the PPA's applicable conditions, together with a class exemption to establish alternative conditions under which such arrangements may operate. Table 1 summarizes the effect of the PPA and this proposed class exemption on permissible investment advice arrangements.

The Department calibrated this proposed regulation to in an effort to protect participants while promoting the affordability of investment advice arrangements operating pursuant to the PPA's statutory exemptive relief, in order that such arrangements will proliferate and thrive, to the benefit of participants.

The PPA's relief (listed at B. in table 1) is conditioned in part on audits. In order to promote the affordability of advice, this proposed regulation provides that audits may rely on a representative sample of similar arrangements. In order to protect participants, this proposed regulation requires that audit reports identifying noncompliance in connection with advice provided to IRA beneficiaries be furnished to the Department.

1—PERMISSIBLE INVESTMENT ADVICE ARRANGEMENTS

Is it permissible for compensation to vary depending on participants' investment decisions?	Person providing advice	Fiduciary adviser entity	Fiduciary advisers' affiliates
A. Absent any exemptive relief:			
1. Except as described at 2. below	No	No	No.
2. Advice is determined solely by a computer model that is provided by an independent entity and over which the fiduciary adviser has no control.	N/a*	Yes	Yes.
B. Under PPA statutory exemption:			
1. Subject to conditions including authorization by a separate fiduciary, independent audits, disclosure, and recordkeeping.	No	No	Yes.
2. Subject to conditions listed above at 1., and advice is provided by a computer model that is certified by an independent expert and satisfies conditions including conformance to investment theories and objectivity.	N/a*	Yes	Yes.
C. Under proposed class exemption:			
1. Subject to conditions including conformance to investment theories, authorization by a separate fiduciary, independent audits, disclosure, and recordkeeping.	No	Yes	Yes.
2. Subject to conditions listed above at 1. and additional conditions including prudence and loyalty, advance provision of benchmark recommendations or educational material, and documentation.	Yes	Yes	Yes.

* Under these arrangements, the investment advice is formulated exclusively by use of the computer model.

The PPA's statutory exemptive relief for investment advice arrangements that use computer models (listed at B.2. in table 1) is conditioned in part on independent expert certification of such models. The expert must meet requirements specified by the Secretary and certifications and renewals thereof must be completed in accordance with rules established by the Secretary. This proposed regulation establishes such requirements and rules.

In advance of formulating these requirements and rules the Department invited and considered extensive public input on the nature, functions, and performance of existing models. The Department also closely examined and road tested some popular models with particular attention to the criteria set forth in section 408(g)(3)(B) of ERISA. The Department came to the conclusion that existing computer models can take into account various information about individuals, their preferences and available investment options and, in its limited attempt to examine whether recommendations provided were optimal, the Department did not find evidence of computer models recommending investment portfolios that have risk return profiles inferior to any individual investment alternative available.

On these bases the Department understands that models capable of satisfying the exemption's conditions are various and evolving. The variety and evolution reflect healthy competition to develop superior products that deliver more value to participants.

The Department sought to calibrate this proposed regulation to nurture such competition while keeping advice affordable and protecting participants' interests. This proposed regulation consequently provides for transparency and procedural rigor but generally does not attempt to specify precise and fixed substantive standards. For example, pursuant to the proposed regulation the experts' qualifications will be reviewed by a fiduciary, and each certification will be documented in detail. The proposed regulation also provides that models may be certified once for similar applications across multiple DC plans or IRAs, rather than separately for each individual application, thereby promoting affordability of arrangements using models.

The Department likewise sought to calibrate this proposed class exemption to protect participants while promoting the affordability of investment advice arrangements operating pursuant to it, in order that such arrangements likewise will proliferate and thrive, to the benefit of participants. As detailed below, the proposed class exemption, by relaxing bars against arrangements that place fiduciary advisers in positions where they have potential conflicts of interest, will increase the variety of investment advice arrangements that are available and potentially lower the cost and promote the marketing of such arrangements, to the benefit of participants. Conditions attached to the proposed class exemption will mitigate the adverse impact of the conflicts and thereby ensure the quality of advice provided pursuant to it.

Availability and Use

Participants have always had the option of obtaining permissible investment advice services directly in the retail market. DC plan sponsors likewise have had the option of obtaining such services in the commercial market and making them available to plan participants and beneficiaries in connection with the plan.

Prior to the 2006 enactment of the PPA, a substantial fraction of DC plan sponsors already made investment advice available to plan participants and

beneficiaries. Today, as the PPA's implementation progresses, many more have begun providing or are gearing up to provide such advice. It is likely that 40 percent or more of DC plan sponsors currently provide access to investment advice either on line, by phone, or in-person. Where offered, approximately 25 percent of participants use advice. In-person advice seems to be offered by the most plan sponsors. On-line advice and to a lesser degree telephone advice are favored more by large sponsors. Smaller plan sponsors appear to offer advice generally and in-person advice in particular more frequently than larger plan sponsors.[34]

Investment advice is also already used by a substantial fraction of IRA participants, the Department believes. A majority of IRA participants that invest in mutual funds purchase some or all of their funds via a professional financial adviser.[35] Overall 60 percent of U.S. workers and retirees say they use the advice of a financial professional when making retirement savings and investment decisions; 40 percent say this advice was more helpful to them than alternatives.[36] It is not clear how recently this advice was obtained, however: In the same survey just 28 percent say that in the past year they obtained investment advice from a professional financial adviser who was paid through fees or commissions.[37]

The new statutory exemptive relief provided by the PPA is expected to increase the availability of advice, but it is too early to observe by how much.[38] The Department believes that absent this proposed class exemption some segments of the plan and participant market will lack adequate access to quality, affordable investment advice. Some potential fiduciary advisers will be deterred from entering the market by the complexity of advice arrangements that conform to the conditions of the PPA's statutory exemptive relief.[39] Some plan sponsors and participants will be deterred by the cost of such arrangements,[40] or by dissatisfaction with the types of advice arrangements that are available at lower costs, such as automated computer investment advice programs.[41] As a result some DC plan sponsors will not offer advice, and where it is offered some participants will not use it.[42] IRA beneficiaries may face similar obstacles to obtaining affordable, quality investment advice.

From the point of view of DC plan sponsors, the PPA and this proposed class exemption could help relieve certain concerns that have impeded some from providing investment advice in the past. A few years prior to the enactment of the PPA less than one in four surveyed DC plan sponsors provided advice, according to one survey.[43] Those not providing advice were asked to cite reasons and rate the reasons' importance on a 0-to-5 scale. Two reasons cited by large majorities and rated moderately important might be ameliorated by this proposed class exemption: ''Fiduciary concern about ensuring that the advice provider has no conflict of interest''[44] (cited by 84 percent and rated 3.1) and ''cost of providing advice''[45] (cited by 69 percent and rated 2.0).[46] In another pre-PPA survey 35 percent of DC plan sponsors not offering advice cited cost as a reason.[47]

From the point of view of prospective fiduciary advisers whose business models involve conflicts—*e.g.*, who are compensated by the companies that manufacture, manage, and/or trade the investment products that they recommend—the PPA and this proposed class exemption grant conditional access to a very large and

[34] This assessment is based on the Department's reading of Hewitt Associates LLC, *Survey Findings: Hot Topics in Retirement, 2007* (2007); Profit Sharing/401(k) Council of America, *50th Annual Survey of Profit Sharing and 401(k) Plans* (2007); and Deloitte Development LLC, *Annual 401(k) Benchmarking Survey, 2005/2006 Edition* (2006). In addition to investment advice, a majority of sponsors also provide one or more other types of support to participants' investment decisions. Other types of support include providing general investment education via seminars or written materials, offering one-stop, pre-mixed investment alternatives such as lifestyle funds, and offering managed accounts.

[35] Eighty-two percent of mutual fund shareholders who hold funds outside of DC plans purchase some or all of their funds from a professional financial adviser such as a full-service broker, independent financial planner, bank or savings institution representative, insurance agent, or accountant (see, *e.g.*, Victoria Leonard-Chambers & Michael Bogdan, *Why Do Mutual Fund Investors Use Professional Financial Advisers?,* Investment Company Institute Research Fundamentals, Volume 16, Number 1 (April 2007)). Because families owning IRAs outnumber those owning pooled investment vehicles outside of retirement accounts (see, *e.g.*, Brian K. Bucks *et al., Recent Changes in U.S. Family Finances: Evidence from the 2001 and 2004 Survey of Consumer Finances,* Federal Reserve Bulletin 92 A1, A1–A38 (2006)), it is reasonable to conclude that a large majority of IRA beneficiaries who invest in mutual funds purchase them via such professionals. The Department has no basis to estimate the fraction of these beneficiaries that receive true investment advice from such professionals, however. It is possible that some make their purchase decisions without receiving any recommendation or material guidance from the professional making the sale.

[36] Alternatives including advice of peers, written plan materials, print media, television and radio, seminars, software, on-line information or advice, and retirement benefit statements were all less likely to be characterized as ''most helpful.''

[37] See, *e.g.*, Employee Benefit Research Institute, *2007 Retirement Confidence Survey, Wave XVII,* Posted Questionnaire (Jan. 2007).

[38] The statutory exemptive relief for investment advice provided by the PPA generally became effective for advice provided after December 31, 2006. In February 2007 EBSA issued guidance on the new statutory exemptive relief for arrangements using fiduciary advisers whose affiliates' revenue might vary depending on the fiduciary advisers' fiduciary acts. It is likely that some such arrangements exist today, and that more will in the future. The PPA also provided relief for arrangements that provide advice via independently certified computer models. The PPA withheld this exemptive relief in connection with IRAs, however, unless and until the Department found and reported to Congress that a model satisfying certain criteria exists. Concurrent with issuance of this proposed class exemption, the Department has reached this finding and reported it to Congress. Therefore statutory relief for this latter type arrangement is just now being extended to IRAs. In addition, the PPA provides that the Department will by regulation specify the process by which computer models will be certified. Concurrent with issuance of this proposed class exemption, the Department is proposing such a regulation. Given this timing it is unlikely that many such latter type arrangements yet exist.

[39] Such complexity can include the need to enlist an adviser who is independent of or merely affiliated with the plan's or IRA's investment manager, in order to avoid direct exposure of the adviser to potential conflicts.

[40] As discussed below, arrangements that avoid potential conflicts may entail higher or more visible costs.

[41] In one survey of DC plan sponsors, among those offering investment advice, ''access to financial counselors in person'' was rated most effective, followed by ''access to financial counselors via telephone.'' ''Web-based'' advice received the lowest effectiveness ratings (see, *e.g.*, Deloitte Development LLC, *Annual 401(k) Benchmarking Survey, 2005/2006 Edition* (2006)). This finding is corroborated by another survey, in which in-person advice appears to be used by participants more often than advice delivered via the Internet (see, *e.g.*, Profit Sharing/401(k) Council of America, *Investment Advice Survey 2001* (2001)).

[42] Where investment advice is available to DC plan participants, only one in four uses it, according to one plan sponsor survey (see, *e.g.*, Profit Sharing/401(k) Council of America, *50th Annual Survey of Profit Sharing and 401(k) Plans* (2007)). On-line advice appeals more to higher-salaried, full-time workers (see, *e.g.*, Julie Agnew, *Personalized Retirement Advice and Managed Accounts: Who Uses Them and How Does Advice Affect Behavior in 401(k) Plans?,* Center for Retirement Research Working Paper 2006–9 (2006)). In one survey, two-thirds of workers and 85 percent of retirees expressed discomfort with ''obtaining advice from financial professionals on-line. This raises the possibility that many participants, perhaps especially lower-paid, part-time participants, may be underserved if the regulatory environment excessively favors on-line advice.

[43] See, *e.g.*, Profit Sharing/401(k) Council of America, *Investment Advice Survey 2001* (2001).

[44] Both the PPA and this proposed class exemption extend conditional relief from ERISA's prohibited transaction provisions, but neither relieves plan fiduciaries of their general obligations under ERISA.

[45] The cost of advice is discussed further immediately below.

[46] Other fiduciary concerns, cited more frequently and rated more important, are not addressed by this proposed class exemption.

[47] See, *e.g.*, Deloitte Development LLC, *Annual 401(k) Benchmarking Survey, 2005/2006 Edition* (2006).

fast growing new market segment.[48] These advisers might be in a position to offer their services at low or no direct cost to the companies' DC plan and IRA clients (relying instead on compensation from the companies). They might market their services to the companies' clients more actively than have independent advisers historically.

For purposes of this impact assessment, the Department anticipates that owing to the statutory exemptive relief provided by the PPA, advice of some type (on-line, telephone and/or in person) will soon be available to perhaps one-half of DC plan participants, with in-person advice available to perhaps one in four. This proposed class exemption will boost these fractions to perhaps 60 percent and 35 percent, respectively. The Department's assumptions are summarized in Table 2.[49]

2—AVAILABILITY OF ADVICE TO DC PLAN PARTICIPANTS

Policy context	Any advice (computer or live) (percent)	Live advisor (percent)
Pre-PPA	40	20
PPA	50	25
Class exemption	60	35

The effect of investment advice depends not merely on its availability but on its use by DC plan and IRA participants. Do the participants seek advice, and if so do they follow it? According to one survey, among DC plan participants offered investment advice, approximately one in four uses it. There is some evidence that historically in-person advice has achieved higher use rates than on-line advice, with on-line advice appealing more to higher-income participants.[50] In another survey large fractions of workers say they would be very likely (19 percent) or somewhat likely (35 percent) to take advantage of advice provided by the company that manages their employer's DC plan. Of these, two-thirds said they would implement only those recommendations that were in line with their own ideas; 21 percent said they would implement all of the recommendations as long as they trusted the source.[51] In a subsequent survey, among those obtaining investment advice, 36 percent say they implemented ''all'' of the advice, 58 percent ''some,'' and just 5 percent ''none.'' [52]

The PPA and this proposed class exemption together could boost DC plan participants' use of advice where offered, in at least two ways. First, because it appears that in-person advice arrangements are more heavily used than automated computer advice programs, wider availability of in-person advice programs wherein advisers can exercise discretion in formulating personalized advice (rather than merely communicate the recommendations of a computer model)—a likely consequence of this proposed class exemption—might be expected to boost use rates. The shift anticipated by the Department (discussed immediately above) would increase the use rate slightly from 25 percent to 26 percent.[53] Second, if the cost of advice falls, participants who must pay for advice will become more inclined to use it. However, historically employers have usually paid directly for advice, or passed the cost to all participants whether they use advice or not,[54] and as explained below it is unclear by how much the cost of advice will fall. Therefore for purposes of this impact assessment the Department did not take into account any cost-driven increase in use of advice by DC plan participants, but assumed that this proposed class exemption will increase the fraction of DC plan participants using advice where available from 25 percent to 26 percent.[55] Given the Department's assumptions regarding availability of advice to DC plan participants, this translates into an increase in the incidence of advice due to this proposed class exemption from 10 percent to 16 percent.

The PPA and this proposed class exemption could also boost IRA participants' use of advice. As noted above, advisers doing business pursuant to this class exemption are likely to actively market advice services to IRA participants and to offer them reduced prices for such services. The reduced prices will reflect both the availability to advisers of other compensation and possible cost saving in the production and delivery of advice. Advisers doing business pursuant to this proposed class exemption may thereby attract business both from IRA participants who otherwise would be without advice and from IRA participants who otherwise would obtain advice through an arrangement that does not require the relief provided by this proposed class exemption. IRA participants who would otherwise be without advice may obtain advice in response to such marketing and pricing activity because the activity reduces their search cost to find and select an adviser, and/or because the reduced price falls below their reservation price. Likewise, IRA participants who would otherwise have obtained advice via some other arrangement may switch to an arrangement pursuant to the PPA or this proposed class exemption (and may increase the amount of advice services they use) because the advisers' marketing activity broadens their search and/or in pursuit of lower prices.

In proposing this class exemption the Department considered carefully the importance of transparency in pricing. Participants' decisions whether and where to obtain advice should be well informed with respect to the cost associated with alternative arrangements. As a condition of this proposed class exemption an adviser must disclose to the participant certain information regarding other revenue sources. This condition is intended to enable participants to decide whether, where, and how much advice to obtain, in light of the associated direct and indirect costs to them.[56] Therefore the

[48] Combined participant directed DC plan and IRA assets exceed $7 trillion.

[49] The Department based its assumptions on its reading of Hewitt Associates LLC, *Survey Findings: Hot Topics in Retirement, 2007* (2007); Profit Sharing/401(k) Council of America, *50th Annual Survey of Profit Sharing and 401(k) Plans* (2007); and Deloitte Development LLC, *Annual 401(k) Benchmarking Survey, 2005/2006 Edition* (2006).

[50] See, *e.g.*, Profit Sharing/401(k) Council of America, *50th Annual Survey of Profit Sharing and 401(k) Plans* (2007); and Julie Agnew, *Personalized Retirement Advice and Managed Accounts: Who Uses Them and How Does Advice Affect Behavior in 401(k) Plans?*, Center for Retirement Research Working Paper 2006–9 (2006).

[51] See, *e.g.*, Employee Benefit Research Institute, *2007 Retirement Confidence Survey, Wave XVII,* Posted Questionnaire (Jan. 2007). In practice this might translate into a high rate of compliance with recommendations, if recommendations turn out not to diverge too much from participants' own ideas.

[52] See, *e.g.*, Employee Benefit Research Institute, 2008 Retirement Confidence Survey, Wave XVIII, Posted Questionnaire (Jan. 2008).

[53] This assumes that the use rate for where in person advice is available is approximately 50 percent higher (30 percent) as where only on-line or telephone advice is available (20 percent) (see, *e.g.*, Employee Benefit Research Institute, *2007 Retirement Confidence Survey, Wave XVII,* Posted Questionnaire (Jan. 2007)).

[54] See, *e.g.*, Profit Sharing/401(k) Council of America, *Investment Advice Survey 2001* (2001).

[55] One survey found that 64 percent of workers already use professional financial advice when making retirement savings and investment decisions, and that 54 percent are very or somewhat likely to use advice if offered by their employer in connection with a DC plan (see, *e.g.*, Employee Benefit Research Institute, *2007 Retirement Confidence Survey, Wave XVII,* Posted Questionnaire (Jan. 2007)). This seems to suggest a higher baseline rate of advice use than assumed here. However, because the latter fraction is smaller than the former, it is unclear whether this suggests that this proposed class exemption would increase DC plan participants' use of advice by more or less than assumed here.

[56] In particular, participants should be able to adequately compare the prices offered by advisers

Department intends that any cost-driven increase in use of advice by IRA participants will be driven by overall cost decreases and not solely by direct price reductions.

As noted above there is evidence that a large fraction of IRA participants already use advice. For purposes of this assessment the Department assumes that as a result of the PPA and this proposed class exemption the proportion of IRA beneficiaries using advice will increase from one-third to two-thirds. The Department's assumptions regarding use of advice are summarized in table 3.[57]

3—USE OF ADVICE BY DC PLAN AND IRA PARTICIPANTS

Policy context	DC plans		IRA	Dollars advised ($trillions)
	Where offered (percent)	Overall (percent)		
Pre-PPA	25	10	33	$1.7
PPA	25	13	50	2.5
Class exemption	26	16	67	3.2

It seems likely that in practice a large proportion of participants who receive advice will follow that advice either in whole or in part. This is especially likely if the advice turns out to be broadly in line with the participants' own thinking. Nonetheless, some advice will not be followed, and as a result some investment errors will not be corrected. For purposes of this analysis, the Department has assumed that advised participants make investment errors at one-half the rate of unadvised participants. The remaining errors reflect participant failures to follow advice (together with possible flaws in some advice, as discussed immediately below).

Cost

As noted above the PPA and this proposed class exemption are expected to make advice available to participants at a lower direct price, because advisers will be able to rely on alternative revenue sources to compensate their efforts. More importantly, however, the Department believes that the total cost of the advice to participants will be reduced. Bars against transactions wherein fiduciary advisers' and participants' interests may conflict carry costs. Faced with such bars advisers may forgo certain potential economies of scale in production and distribution of financial services that would derive from more vertical and horizontal integration.[58] And to avoid such conflicts they must carefully monitor and calibrate their relationships and compensation arrangements, or incur the opportunity cost associated with exclusive reliance on level fees. The Department therefore expects the PPA and this proposed class exemption to produce cost savings by harnessing economies of scale and by reducing compliance burdens. The Department is unaware of any available empirical basis on which to determine whether or by how much costs might be reduced, however.

Quality

The effect of investment advice also depends on its quality. Good advice can reduce investment errors, steering investors away from higher than necessary expenses and toward optimal trading strategies, broad diversification, and asset allocations consistent with the investors' tastes for risk and return. The Department believes that, although there is no universally accepted single and complete theory of optimal investing, and although there is some evidence of lapses in the quality investment advice,[59] professional advisers'

doing business pursuant to this exemption with those offered by other advisers such as those offering their services for a flat fee.

[57] These assumptions are based on the Department's reading of Employee Benefit Research Institute, *2007 Retirement Confidence Survey, Wave XVII,* Posted Questionnaire (Jan. 2007); Hewitt Associates LLC, *Survey Findings: Hot Topics in Retirement, 2007* (2007); Profit Sharing/401(k) Council of America, *50th Annual Survey of Profit Sharing and 401(k) Plans* (2007); and Deloitte Development LLC, *Annual 401(k) Benchmarking Survey, 2005/2006 Edition* (2006). There are a number of reasons to believe that use of advice will be higher among IRA beneficiaries than DC plan participants. The aforementioned survey reports, read together, generally support this conclusion. In addition, relative to IRA beneficiaries, DC participants may have less need for advice and/or easier access to alternative forms of support for their investment decisions. DC plan participants' choice is usually confined to a limited menu selected by a plan fiduciary, and the menu may include one-stop alternatives such as target date funds that may mitigate the need for advice. Their plan or employer may provide general financial and investment education in the form of printed material or seminars. They often make initial investment decisions (sometimes by default) before contributing to the plan so the decisions' impact may seem small. Finally, the availability of advice in connection with the plan is intermediated by the plan sponsor and fiduciary. In contrast, IRA beneficiaries generally have wider choice and are more likely to be without employer-provided support for their decisions. Decision points may more often occur when account balances are large, such as when rolling a large DC plan balance into an IRA or when retiring. Finally, the availability of advice to IRA beneficiaries is not intermediated by an employer—rather IRA beneficiaries interface directly with the retail market and will thereby be more directly affected by the exemptive relief provided by the PPA and by this proposed class exemption. For all of these reasons IRA beneficiaries may use advice more frequently than DC plan participants.

[58] For example, an adviser employed by an asset manager can share the manager's research instead of buying or producing such research independently.

[59] There is no single, complete, universally accepted theory of optimal investment. Instead there are competing and evolving theories which have much in common (what might be called ''generally accepted'' theories) but also important differences (see, *e.g.*, Martin Wallmeier & Florian Zainhofer, *How to Invest Over the Life Cycle: a Review,* Social Science Research Network Abstract 951167 (Dec. 2006); and Deloitte Financial Advisory Services LLP, *Generally Accepted Investment Theories* (July 11, 2007) (unpublished memorandum, on file with the Department of Labor)). In practice this means that different experts may give different advice; often the differences will be small but occasionally they might be large.

There is some evidence of lapses in the quality of investment advice. Investment advisers' advice does not always conform to generally accepted investment theories. For example, they sometimes neglect investors' debt, or exhibit ''home bias'' toward domestic investment. Home bias may be larger in advice given to more risk averse investors; this conflicts with theory insofar as home bias reduces diversification and therefore increases risk. Investment advisers in some sense have two functions: to provide *investment* advice and to provide *investor* advice. The former ought to conform to financial theories, while the latter involves helping investors overcome behavioral biases and errors. Together these functions may result in a nuanced balance between what the investor theoretically ''should'' choose and what the investor is comfortable choosing (see, *e.g.*, Elisa Cavezzali & Ugo Rigoni, *Investor Profile and Asset Allocation Advice,* Social Science Research Network Abstract 966178 (Feb. 2007)). Some advice computer models and educational material may furnish misleading information regarding risk and consequently may do harm (see, *e.g.*, Zvi Bodie, *An Analysis of Investment Advice to Retirement Plan Participants, in The Pension Challenge: Risk Transfers and Retirement Income Security* 19, 19–32 (Olivia S. Mitchell & Kent Smetters eds., 2003)). Advice computer models generally fail to coordinate financial investments with financial risks associated with individuals' jobs, homes, and health (see, *e.g.*, John Ameriks & Douglas Fore, *Financial Planning: On the Issue of Advice,* Benefits Quarterly, Fourth Quarter 6, 6–14 (2002)). While it is widely agreed that such coordination is important, theories about how this should be done

Continued

recommendations are likely to be superior to unadvised participants' investment practices.[60] It is therefore likely that participants who obtain and follow advice, including advice provided pursuant to the PPA or this proposed class exemption and advice provided under alternative permissible arrangements, will substantially reduce their investment mistakes and thereby derive substantial financial benefits and improve their welfare.

In its effort to ensure the quality of advice, the Department carefully considered the substantial risks attendant to opportunities for self-dealing that may exist among fiduciary advisers doing business pursuant to the PPA or this proposed class exemption. There is evidence that advisers sometimes seize such opportunities and thereby reap profit at investors' expense.[61] The provisions of this proposed regulation and conditions attached to this proposed class exemption are intended to guard against these risks while keeping advice affordable.[62]

For purposes of this analysis, the Department has assumed that advised participants make investment errors at one-half the rate of unadvised participants. The remaining errors reflect possible flaws in some advice (together with participant failures to follow advice, discussed immediately above).[63] Additionally for purposes of this analysis the Department assumes that all permissible advice arrangements (including those operating pursuant to exemptive relief provided by the PPA and those operating pursuant to this proposed class exemption) deliver

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continue to evolve (see, *e.g.*, Günter Franke *et al.*, *Non-Market Wealth, Background Risk and Portfolio Choice,* Social Science Research Network Abstract 968096 (Mar. 2007)). Typical advice as reflected in target-date funds conforms to some financial theories but conflicts with others (see, *e.g.*, Luis M. Viceira, *Life-Cycle Funds,* Social Science Research Network Abstract 988362 (May 2007)).

[60] Rene Fischer & Ralf Gerhardt, *Investment Mistakes of Individual Investors and the Impact of Financial Advice,* Science Research Network Abstract 1009196 (Aug. 2007) ''present financial advice as (potentially) correcting'' a variety of investment mistakes that left uncorrected ''lead to considerable welfare losses.''

[61] These risks consist of the possibility that some advisers will pursue profit by dispensing advice that increases their own revenue at the expense of participants' interests.

Consideration of these risks is especially important because advice pursuant to this proposed class exemption, while extending to many participants who otherwise would invest without guidance or support, may also extend to many others who absent this class exemption would have benefited from alternative forms of support for their investment decisions, such as alternative permissible advice arrangements, target-date funds, managed accounts, or automatic rebalancing.

In considering these risks the Department devoted separate attention to the application of this proposed class exemption to IRAs. In contrast to DC plan participants, IRA participants may be more vulnerable to risks attendant to conflicts of interest insofar as they: (1) May include more retirees, who may be in greater need of advice, but who also may be more vulnerable to abusive practices (see, *e.g.*, Phyllis C. Borzi & Martha Priddy Patterson, *Regulating Markets for Retirement Payouts: Solvency, Supervision and Credibility,* Pension Research Council Working Paper PRC WP2007–21 (Sept. 2007)); (2) are not represented by a plan fiduciary, independent of the adviser and connected to their interests via an employment relationship, who selects and monitors the advice arrangement and pre-screens the menu of investment options for quality; and (3) may not, under the conditions of this proposed class exemption, have the benefit of specific advice provided by an independent or independently-certified computer model to compare with (and possibly follow in lieu of) advice delivered pursuant to the proposed class exemption. In addition, while advisers to DC plan participants are subject to standards of fiduciary conduct and attendant liability under Title I of ERISA, advisers to IRA beneficiaries are not. Finally, the Department's authority to enforce the conditions of this proposed exemption generally extends only to DC plans and not to IRAs. On the other hand, IRA beneficiaries' vulnerability to risks attendant to conflicts of interest may be mitigated by their ability to make rational and well informed purchases in a vibrant, competitive market for investment advice and other financial products and services in which some vendors will offer unconflicted advice.

The Department believes that absent effective controls conflicts can sometimes bias advice, although it is unclear how much or in exactly what ways. Biased advice may be less beneficial to investors than unbiased advice, or possibly even harmful in some cases.

There is a theoretical basis to believe that investors may be harmed (or may benefit less) where managers pay intermediary advisers for inflows, and that such payments may increase the role of intermediaries (fewer investors may invest directly) (see, *e.g.*, Neal M. Stoughton *et al.*, *Intermediated Investment Management,* Social Science Research Network Abstract 966255 (Mar. 2007)). This suggests that advisers whose fees are not level relative to their clients' investment elections may give biased advice that enriches managers at investors' expense (the motivation for and potential to profit from conflicts and bias may attach more to the manager who compensates the adviser than to the adviser). It also suggests that advisers doing business pursuant to this proposed class exemption might displace alternative forms of investment decision support.

According to one empirical study, ''there exists conflict of interests between load fund investors and brokers and financial advisers: brokers and financial advisers apparently serve their own interests by guiding investors into funds with higher loads, which generate higher income to the brokers and financial advisers but increase the expenses of investors.'' High load funds have larger inflows than low load funds with otherwise similar performance. Recent increases in fund loads suggest that funds are seeking favor from brokers and advisers (see, *e.g.*, Xinge Zhao, *The Role of Brokers and Financial Advisors Behind Investment Into Load Funds,* China Europe International Business School Working Paper (Dec. 2005), *at http://www.ceibs.edu/faculty/zxinge/brokerrole-zhao.pdf*). Another study reaches similar conclusions. ''Relative to direct-sold funds, broker-sold funds deliver lower risk-adjusted returns, even before subtracting distribution costs. * * * Further, broker-sold funds exhibit no more skill at aggregate-level asset allocation than do funds sold through the direct channel.'' Even before accounting for the higher distribution expenses, the underperformance cost investors $4.6 billion in 2004. Brokers devote more effort to selling funds that generate more revenue for them (see Daniel B. Bergstresser *et al.*, *Assessing the Costs and Benefits of Brokers in the Mutual Fund Industry,* forthcoming in The Review of Financial Studies).

Yet another study finds that ''investors who transact through investment professionals that are compensated through conventional distribution channels incur substantially poorer timing performance than investors who purchase pure no load funds.'' The underperformance amounts to approximately 100 or 150 basis points (see, *e.g.*, Mercer Bullard *et al.*, *Investor Timing and Fund Distribution Channels,* Social Science Research Network Abstract 1070545 (Dec. 2007)).

Some other studies are less conclusive. For example, one finds that captive brokers add more value for investors in purchasing funds, while unaffiliated brokers add the most value in redeeming them. Direct, no-load investors' redemptions are the least sensitive to performance. This study also finds that higher payments from fund companies to unaffiliated brokers buys some inflows for funds (see, *e.g.*, Susan Christoffersen *et al.*, *The Economics of Mutual-Fund Brokerage: Evidence from the Cross Section of Investment Channels,* Social Science Research Network Abstract 687522 (Dec. 2005)).

[62] The Department has no basis to estimate how much risk might remain. However the Department notes that the safeguards associated with the PPA and this class exemption are likely to be stronger than those associated with available research studies, cited above, that quantify substantial losses to investors. First, advisers to DC plan participants are subject to ERISA's fiduciary standards. Second, the PPA and this class exemption provide substantive conditions including unbiasedness, together with procedural protections such as provision of advice generated by computer models that are certified by independent experts, documentation of bases for advice, and audits of investment advice programs' conformance to applicable substantive conditions. Such protections generally are not provided in other U.S. contexts. For a discussion of protections applicable where advice is delivered by investment advisers or brokers to investors outside of IRAs and ERISA-covered retirement plans, see Angela A. Hung *et al.*, *Investor and Industry Perspectives on Investment Advisers and Broker-Dealers,* RAND Corporation Technical Report (2008), at *http://www.sec.gov/news/press/2008/2008–1_randiabdreport.pdf.*

[63] Whether advice corrects errors depends on whether the advice is followed and whether it is good. There is reason to believe that many people receiving advice will follow it. In a 2008 survey, among those obtaining investment advice, 36 percent say they implemented ''all'' of the advice, 58 percent ''some,'' and just 5 percent ''none'' (Employee Benefit Research Institute, *2008 Retirement Confidence Survey, Wave XVII,* Posted Questionnaire (Jan. 2008)). There is also reason to believe that good advice will be available. According to Bluethgen, *et al.*, *High-Quality Financial Advice Wanted!,* Social Science Research Network Abstract 1102445 (Feb. 2008), ''There is a high degree of heterogeneity in quality among financial advisors * * * the extent to which advisors receive compensation in the form of fixed fees instead of sales commissions as well as the extent to which advisors exhibit a high degree of rationality in decision making are predictive of high-quality financial advice.'' According to Bluethgen, *et al.*, *Financial Advice and Individual Investors' Portfolios,* Social Science Research Network Abstract 968197 (Mar. 2008), ''advice enhances portfolio diversification, makes investor portfolios more congruent with predefined model portfolios, and increases investors' fees and expenses. Our empirical evidence is broadly in line with honest financial advice.''

advice of similar quality and effectiveness.

Benefits

The Department expects the PPA and this proposed class exemption to reduce investment errors to the benefit of participants. As noted above, prior to implementation of the PPA, investment mistakes cost participants $109 billion or more annually. Increased use of investment advice under the PPA will reduce such mistakes by $7 billion, and this proposed class exemption will reduce them by another $7 billion, the Department estimates. Altogether after implementation of this proposed class exemption, use of investment advice by DC plan and IRA participants will eliminate $29 billion worth of investment errors annually. The Department's estimates of investment errors and reductions from investment advice are summarized in table 4.

4—INVESTMENT ERRORS AND IMPACT OF ADVICE ($BILLIONS, ANNUAL)

Policy context	Remaining errors	Errors eliminated by advice	
		Incremental	Cumulative
No advice	$124	$0	$0
Pre-PPA advice only	109	15	15
PPA	102	7	22
Class exemption	95	7	29

Costs

Participant gains from investment advice must be weighed against the cost of that advice. Different types of advice may come with different costs. For example, advice generated by an automated computer program may be less costly than advice provided by a personal adviser. For purposes of this analysis the Department assumed that in the context of a DC plan, computer generated advice costs 10 basis points annually, while adviser provided advice costs 20 basis points. In connection with an IRA the corresponding assumptions are 15 and 30 basis points. These assumptions are reasonable in light of information available to the Department about the cost of various existing advice arrangements. On this basis the Department estimates the cost of advice as summarized in table 5.[64]

5—COST OF ADVICE

	Pre-PPA	PPA	Class exemption
Incremental:			
Advice cost ($billions)	$3.8	$1.8	$2.3
Advice cost rate (bps, average)	23	23	29
Error reduced per $1 of advice, average	$3.90	$3.80	$3.10
Cumulative (combined with policies to the left):			
Advice cost ($billions)	$3.8	$5.6	$7.9
Advice cost rate (bps, average)	23	23	24
Error reduced per $1 of advice, average	$3.90	$3.90	$3.70

Alternatives

In formulating this proposed regulation and proposed class exemption, the Department considered several alternative approaches.

Specific Substantive Standards for Model Certification

This proposed regulation provides mostly procedural standards for the certification of computer models pursuant to PPA's statutory exemptive relief. In crafting these provisions the Department carefully considered whether to establish specific substantive standards as well.

Computer models are evolving, driven by advances in information technology and financial theories, and by market competition. A recipe for testing the robustness of one current technology might not be effective when applied to a future technology. Ongoing refinements and revisions to financial theories, the product of healthy competition among ideas, would soon belie any specification of generally accepted theory that might be enshrined in regulation. The Department therefore believes that a substantive standard generally would not serve to protect participants but instead might diminish the benefits of the PPA's relief for arrangements using models. However, the Department invites comments on the advantages and disadvantages of a more substantive standard than what is proposed, and asks for suggestions for what a more substantive standard might include.

Deferring Action on Class Exemption

The Department considered deferring proposing a class exemption for a year or more in order to observe the market impact of the exemptive relief provided by the PPA. This might have provided fuller information on the degree to which some market segments would remain underserved by advice and on the barriers responsible for such ongoing under service, and thereby assisted the Department's effort to determine whether and how to provide additional exemptive relief.

However, the Department is concerned that deferring action might delay the proliferation of advice and prolong correctable investment errors and believes that the need for additional exemptive relief is already adequately

[64] The Department notes that costs probably often will not be distributed across advised participants in proportion to the size of their accounts. Rather, it is likely that some costs of providing advice are fixed relative to account size, so the cost borne by small account holders probably will be larger in relation to account size than that borne by large account holders. The average estimates reported in table 4 are dollar weighted. For the average participant, the basis point cost will be higher than this dollar weighted average, and the amount by which investment errors are reduced per dollar of advice will be lower.

clear. The exemptive relief provided by the PPA does not embrace business models that occupy large parts of the non-IRA retail market,[65] and therefore may leave major segments of the DC plan and IRA markets underserved. In addition, by excluding popular business models, the PPA's exemptive relief by itself would tilt the playing field in favor of other business models, which may sometimes be more expensive or less beneficial. This raises the possibility that some segments of the market would be inefficiently served. This proposed class exemption will level the playing field for competing business models and thereby promote efficiency in the market for investment advice.

Level Fee Condition

The PPA provides conditional exemptive relief for advice arrangements wherein the revenue of a fiduciary adviser's affiliates varies on the basis of advised participants' investment decisions, but not to arrangements wherein the revenue of the fiduciary adviser itself so varies. This proposed class exemption extends conditional relief to the latter.

The Department considered including as a mandatory condition of this proposed class exemption a requirement that the compensation received by the person providing the advice on behalf of the fiduciary adviser does not vary on the basis of participants' investment decisions. Such a condition might ease enforcement of the exemption's conditions, and might reduce the risks attendant to conflicts of interest that may exist among advisers doing business pursuant to the proposed class exemption. But it also would exclude from exemptive relief popular business models that are well established in the non-IRA retail market and that operate without similar compensation requirements, and therefore might unduly impair the availability of advice. Therefore Department elected to make this ''level fee'' condition [66] one of two alternative conditions,[67] thereby allowing the person's compensation to vary as long as the other condition is met. The other condition provides alternative protections against the risks attendant to conflicts of interest.

Model Generated Advice for IRA Beneficiaries

The Department considered including as part of the immediately aforementioned alternative condition a requirement that IRA beneficiaries always be provided with specific, model generated investment recommendations, similar to those which under the condition must be provided to DC plan participants.[68] However the Department believes that such a requirement sometimes might be neither practical nor effective as applied to IRAs. It might not be practical because, while such models exist, their availability, affordability and effectiveness are not yet proven in all segments of the IRA market. It might not be effective because the wide range of investment options open to most IRA beneficiaries could make comparisons of model generated advice with the advisers' recommendations difficult for beneficiaries. Therefore the conditions of this proposed class exemption allow that IRA beneficiaries may under certain circumstances be provided with educational material or recommendations on asset allocation across asset classes rather than with specific, model generated investment recommendations.[69]

Uncertainty

The Department is highly confident in its conclusion that investment errors are common and often large, producing large avoidable losses (including foregone earnings) for participants. It is also confident that participants can reduce errors substantially by obtaining and following good advice. While the precise magnitude of the errors and potential reductions therein are uncertain,[70] there is ample evidence that that magnitude is large.

The Department is also confident that this proposed class exemption, by relaxing rules governing arrangements under which advice can be delivered, will promote wider use of advice. However, the Department is uncertain to what extent advice will reach participants and to what extent advice that does reach them will reduce errors. To illustrate that uncertainty, the Department conducted sensitivity tests of how its estimates of the reduction in investment errors attributable to the PPA and this proposed class exemption would change in response to alternative assumptions regarding the availability, use, and quality of advice. Table 6 summarizes the results of these tests.

6—UNCERTAINTY IN ESTIMATE OF INVESTMENT ERROR REDUCTION

Primary estimates denoted *	Impact of PPA	Impact of class exemption	Impact of all advice	Remaining errors
Advice eliminates:				
50% of errors *	$7	$7	$29	$95
75% of errors	11	11	47	86
25% of errors	3	3	14	102
After PPA/class exemption, advice reaches:				
13%/16% of DC and 50%/67% of IRA *	7	7	29	95
15%/21% of DC and 60%/80% of IRA	11	9	35	89
11%/13% of DC and 40%/50% of IRA	3	4	22	102

[65] See, *e.g.*, Victoria Leonard-Chambers & Michael Bogdan, *Why Do Mutual Fund Investors Use Professional Financial Advisers?,* Investment Company Institute Research Fundamentals, Volume 16, Number 1 (April 2007); and Employee Benefit Research Institute, *2007 Retirement Confidence Survey, Wave XVII,* Posted Questionnaire (Jan. 2007).

[66] See paragraph (f).

[67] The alternative condition is at paragraph (e). Paragraph (d) provides that the two are alternatives.

[68] See paragraph (e)(1).

[69] See paragraph (e)(2).

[70] The incidence and magnitude of investment errors is uncertain. Because errors are generally measured with reference to some optimal benchmark, the evolving character of investment theory contributes to this uncertainty. For a given level of incidence and effectiveness of advice, the reduction in errors will be proportionate to the errors reduced. The Department did not attempt to estimate the magnitude of losses from inappropriate risk or excess taxes, so its estimate of this proposed class exemption's impact omit potential reductions in such errors. As noted above, the Department's estimate of higher than necessary expenses is conservative in light of referenced literature and omits certain less visible expenses such as mutual funds' internal transaction costs. Its estimates of losses from poor trading strategies and inadequate diversification are moderate, if not conservative, taking account of the losses that were measured in the referenced studies. The Department believes that the combined magnitude of investment errors, and therefore of the reduction in such errors that can be expected from wider use of advice, is at least as large as reported here, and possibly much larger.

The Department is uncertain whether the magnitude and incidence of investment errors and the potential for correction of such errors in the context of IRAs might differ from that in the context of ERISA-covered DC plans. If a DC plan's menu of investment options is efficient then the incidence and/or magnitude of errors might be smaller than in the IRA context. If it is inefficient then errors might be more numerous and/or larger, but the potential for correcting them might be constrained. As noted earlier, evidence on the efficiency of existing menus is mixed.

The Department is uncertain about the mix of advice and other support arrangements that will compose the market, and about the relative effectiveness of alternative investment advice arrangements or other means of supporting participants' investment decisions. For example, to what extent will arrangements pursuant to this proposed class exemption displace alternative arrangements? Will advice arrangements operating pursuant to this proposed class exemption be more, less, or equally effective as alternative arrangements?

This analysis has assumed that all types of advice arrangements are equally effective at reducing investment errors, and that none will increase errors (there will be no very bad advice). This assumption may not hold, however, for a number of reasons. For example, as illustrated above in table 1, advisers operating pursuant to different exemptive relief may be subject to different levels of conflicts of interest. Individuals providing advice pursuant to this proposed class exemption may face particularly direct conflicts, in the form of opportunities to tailor advice to directly profit themselves at participants' expense. The Department's consideration of this risk was detailed above.

The conditions attached to exemptive relief under the PPA and this proposed class exemption are intended to control this risk while keeping advice affordable. The Department notes that if users of advice are fully informed and rational then more cost effective arrangements will dominate the market. This proposed class exemption establishes conditions to ensure that prospective users of advice available pursuant to it will have the opportunity to become fully informed.

The Department is uncertain about the potential magnitude of any transitional costs associated with this proposed regulation and proposed class exemption. These might include costs associated with efforts of prospective fiduciary advisers to adapt their business practices to the applicable conditions. They might also include transaction costs associated with initial implementation of investment recommendations by newly advised participants.

Another source of uncertainty involves potential indirect downstream effects of this proposed regulation and proposed class exemption. Investment advice may sometimes come packaged with broader financial advice, which may include advice on how much to contribute to a DC plan. The Department has no basis to estimate the incidence of such broad advice or its effects, but notes that those effects could be large. The opening of large new markets to a variety of investment advice arrangements to which they were heretofore closed may affect the evolution of investment advice products and services and related technologies and their distribution channels and respective market shares. Other possible indirect effects that the Department lacks bases to estimate include financial market impacts of changes in investor behavior and related macroeconomic effects.

The Department invites comments on how to improve this analysis, with particular attention to the assessment and explanation of attendant uncertainty, and how such analysis could be carried out. Comments that include specific suggestions or data to help support our analysis of impacts and the characterization of uncertainty would be especially useful.

Executive Order 12866

Under Executive Order 12866, the Department must determine whether a regulatory action is significant and therefore subject to the requirements of the Executive Order and review by the Office of Management and Budget (OMB). This action, comprising this proposed regulation and proposed class exemption, is economically significant under section 3(f)(1) of the Executive Order because it is likely to have an effect on the economy of $100 million or more in any one year. Accordingly, the Department undertook the foregoing analysis of the actions' impact. On that basis the Department believes that the actions' benefits justify their costs.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and are likely to have a significant economic impact on a substantial number of small entities. For purposes of analysis under the RFA, the Department proposes to continue its usual practice of considering a small entity to be an employee benefit plan with fewer than 100 participants.[71] The Department estimates that approximately 100,000 small plans, a significant number, will voluntarily begin offering investment advice to participants as a result of this proposed regulation and proposed class exemption.

The primary effect of this proposed regulation and proposed class exemption will be to reduce participants' investment errors. This is an effect on participants rather than on plans. The impact on plans generally will be limited to increasing the means by which they may make advice available to participants, and this impact will be similar and proportionate for small and large plans. Therefore the Department certifies that the impact on small entities will not be significant. Pursuant to this certification the Department has refrained from preparing an Initial Regulatory Flexibility Analysis of this proposed regulation and proposed class exemption. The Department invites the public to comment on its definition of small entities and its certification.

Notwithstanding this certification, the Department did separately consider the impact of this proposed regulation and proposed class exemption on participants in small plans.

As noted earlier, prior to implementation of the PPA smaller plan sponsors offered advice generally, and in-person advice in particular, more frequently than larger plan sponsors. The Department believes that exemptive relief provided by both the PPA and this proposed class exemption will promote wider offering of advice by small and large plans sponsors alike. Accordingly the Department estimated the impacts on small plans assuming that they generally will be proportionate to those on large plans. However, because smaller plan sponsors are more likely to offer in-person advice, their average cost for advice and the proportion of participants using advice may both be higher. The Department estimates that the PPA and this proposed class exemption will reduce small DC plan participant investment errors

[71] EBSA requests comments on the appropriateness of the size standard used in evaluating the impact of these proposed rules on small entities. EBSA has consulted with the SBA Office of Advocacy concerning use of this participant count standard for RFA purposes. *See* 13 CFR 121.903(c).

respectively by $105 million or more and $126 million or more, at respective costs of $22 million and $28 million. The estimated impacts on small plans and their participants are summarized on table 7.

7—SMALL DC PLAN PARTICIPANT IMPACTS

	Pre-PPA	PPA	Class exemption
Dollars advised ($ billions)	$47	$59	$73
Investment errors ($ billions)	$8.0	$7.9	$7.8
Incremental:			
Errors reduced by advice ($ millions)	$421	$105	$126
Advice cost ($ millions)	$86	$22	$28
Advice cost rate (bps, average)	18	18	20
Error reduced per $1 of advice, average	$4.88	$4.88	$4.46
Cumulative (combined with policies to the left):			
Errors reduced by advice ($ millions)	$421	$526	$652
Advice cost ($ millions)	$86	$108	$136
Advice cost rate (bps, average)	18	18	19
Error reduced per $1 of advice, average	$4.88	$4.88	$4.79

Congressional Review Act

This notice of proposed rulemaking is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and, if finalized, will be transmitted to the Congress and the Comptroller General for review.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, the notice of proposed rulemaking does not include any federal mandate that will result in expenditures by state, local, or tribal governments in the aggregate of more than $100 million, adjusted for inflation, or increase expenditures by the private sector of more than $100 million, adjusted for inflation.

Federalism Statement

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have substantial direct effects on the States, the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This proposed rule does not have federalism implications because it has no substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The requirements implemented in this proposed rule do not alter the fundamental provisions of the statute with respect to employee benefit plans, and as such would have no implications for the States or the relationship or distribution of power between the national government and the States.

Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department of Labor conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that the public understands the Department's collection instructions; respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Currently, EBSA is soliciting comments concerning the proposed information collection request (ICR) included in the Proposed Class Exemption for the Provision of Investment Advice to Participants and Beneficiaries of Self-Directed Individual Account Plans and IRAs and in the Proposed Investment Advice Regulation (Proposed Investment Advice Initiative). A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov*. PRA Addressee: Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–5333. These are not toll-free numbers.

The Department has submitted a copy of the Proposed Investment Advice Initiative to the Office of Management and Budget (OMB) in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Department and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Attention: Desk Officer for the Employee Benefits Security Administration. OMB requests that comments be received within 30 days of publication of the Proposed Investment Advice Initiative to ensure their

consideration. Please note that comments submitted to OMB are a matter of public record.

The Department notes that a federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. EBSA will publish a notice of OMB's action at the final rule stage.

In order to use the statutory exemption and/or the class exemption [72] to provide investment advice to participants and beneficiaries in participant-directed defined contribution (DC) plans and beneficiaries of individual retirement accounts (IRAs) (collectively hereafter, ''participants''), investment advisory firms would be required to make disclosures to participants and hire an independent auditor every year. Investment advice firms following the conditions of the exemption based on disclosure of computer model-generated investments would be required to obtain certification of the model from an eligible investment expert.[73] The class exemption conditions relief on establishing written policies and procedures and both exemptions impose recordkeeping requirements.[74] These paperwork requirements are designed to safeguard the interests of participants in connection with investment advice covered by the exemptions.

The Department has made several specific basic assumptions in order to establish a reasonable estimate of the paperwork burden of this information collection:

• The Department assumes that 80% of disclosures [75] will be distributed electronically via means already in existence as a usual and customary business practice and the costs arising from electronic distribution will be negligible.[76]

• The Department assumes that investment advisory firms will use existing in-house resources to prepare the policies and procedures and most disclosures and to maintain the recordkeeping systems. This assumption does not apply to the computer model certification, the audit or the computer program used to generate disclosures for IRA participants.

• The Department assumes a combination of personnel will perform the information collections with an hourly wage rate for 2008 of $79 for a financial manager, $21 for clerical personnel, $109 for a legal professional, and $67 for a computer programmer.[77]

The Statutory Exemption

The Department assumes that approximately 16,000 investment advisory firms [78] (including broker-dealers) will take advantage of this statutory exemption to provide advice to participants.[79] The number of investment advisory firms using this statutory exemptive relief is assumed to be constant over time. The Department estimates that under the statutory exemption approximately 52,000 DC plans will seek to provide advice to their participants and beneficiaries. These DC plans represent approximately 6,611,000 participants and beneficiaries, of which approximately 1,487,000 will seek advice from the investment advisory firm servicing their employer-sponsored retirement investment plan. IRAs can also make use of this statutory exemption, and the Department estimates that approximately 8.7 million IRA beneficiaries will seek advice under this statutory exemption.[80]

Disclosures to Participants

In general, under section 2550.408(g)–1(g) of the proposal, a fiduciary adviser is required to furnish detailed information to a participant about an advice arrangement before initially providing investment advice, annually, upon participant request and if there is any material change to the information. The information includes the following: The relationship between the adviser and the parties that developed the investment advice program or selected the investment options available under the DC plan or IRA; to the extent such information is not otherwise provided, the past performance and historical rates of return of investments available under the DC plan or IRA; all fees and other compensation the fiduciary adviser or any affiliate is to receive in connection with the provision of investment advice or in connection with the investment; the fiduciary adviser's material relationship, if any, to any investment under the arrangement; the types of services the fiduciary adviser provides in connection with the provision of investment advice; the manner in which participant information may be used or disclosed; an acknowledgement that the fiduciary adviser is acting as a fiduciary of the DC Plan or IRA in connection with providing the investment advice; and notice that the recipient of the advice may separately arrange for advice from

[72] The Department assumes that all advisory firms use both the statutory exemption and the class exemption.

[73] All costs associated with model certification are assigned to the statutory exemption.

[74] All costs associated with composing written policies and procedures are assigned to the class exemption.

[75] This estimate is derived from Current Population Survey October 2003 School Supplement probit equations applied to the February 2005 Contingent Worker Supplement. These equations show that approximately 81 percent of workers aged 19 to 65 had internet access either at home or at work in 2005. The Department further assumes that one percent of these participants will elect to receive paper documents instead of electronic, thus 20 percent of participants receive disclosures through paper media.

[76] The Department assumes that plans will deliver disclosures electronically in compliance with the Department's rules relating to the use of electronic media (29 CFR 2520.104b–1(c)). The Department has not estimated any additional burden for plans to receive affirmative consents from participants to receive required disclosures electronically. The Department welcomes comments on this assumption.

[77] Hourly wage estimates are based on data from the Bureau of Labor Statistics Occupational Employment Survey (May 2005) and the Bureau of Labor Statistics Employment Cost Index (Sept. 2006). All hourly wage rates include wages and benefits. Clerical wage and benefits estimates are based on metropolitan wage rates for executive secretaries and administrative assistants. Financial manager wage and benefits estimates are based on metropolitan wage estimates for financial managers. Legal professional wage and benefits estimates are based on metropolitan wage rates for lawyers. Computer programmer wage and benefits estimates are based on metropolitan wage rates for professional computer programmers.

[78] Unless otherwise noted, numbers are rounded to the nearest 1,000.

[79] This estimate is derived from Angela A. Hung *et al., Investor and Industry Perspectives on Investment Advisers and Broker-Dealers*, RAND Corporation Technical Report (2008), at *http://www.sec.gov/news/press/2008/2008-1_randiabdreport.pdf*.

[80] To be conservative, the Department assumes that all 16,000 advisory firms give advice pursuant to both the statutory and class exemptions as they all will have some clients who request only level fee or computer model advice under the statutory exemption and other clients who request off-model advice under the class exemption. The Department estimates that there are approximately 209,000 DC plans that are currently offering advice (pre-statutory exemption advice), that after the statutory exemption is published approximately 261,000 DC plans will offer advice and that after the class exemption is published approximately 314,000 DC plans will offer advice. The Department cannot determine which of these plans will be offering advice under pre-statutory exemption, statutory exemption or class exemption conditions; thus the Department decided to apply costs to the statutory and class exemptions based on the incremental change in the number of DC plans offering advice. This method is also applied to the number of IRA beneficiaries receiving advice; the Department estimates that approximately 16.8 million IRA beneficiaries received advice under pre-statutory exemption conditions, approximately 25.5 million will receive advice under statutory exemption conditions and approximately 34.0 will receive advice under class exemption conditions. The Department welcomes comments on this assumption.

another adviser that could have no relationship to, and receive no fees in connection with, the investments. If applicable, the fiduciary adviser also furnishes in writing to the DC plan fiduciary an election, as permitted under the regulation, to be treated as the sole fiduciary providing investment advice through a computer model to an ERISA-covered DC plan participant. The Department assumes that investment advisory firms will compile all of these notices into a single four-page disclosure package for each participant given advice. As these disclosures are to be given to the participants and are based upon the investments that are recommended, the Department further assumes that these disclosures will be generated at three levels: The investment advisory firm level, the DC plan level and the IRA beneficiary level. The firms will generate a template for each of these disclosures levels.[81]

Preparation of Statutory Exemption Disclosure Package

For the first year (initial) disclosures, the Department assumes that it takes a legal professional approximately six hours per investment advisory firm to prepare disclosures that are common to all of their participants, about 100 hours per investment advisory firm to assist an out-sourced computer programmer in creating computer software that will generate disclosure notices for IRA beneficiaries, and approximately two and one-half hours per DC plan to prepare disclosures that are common to all DC plan participants and beneficiaries in the same DC plan. These hours add up to an hour burden of approximately 1,779,000 hours; at a wage rate of $109 for a legal professional the equivalent cost is approximately $194,792,000.

For the annual updating of disclosures required by Section 2550.408g–1(g)(4)(ii), the Department assumes that the preparation time needed for updating the notices that are the same for all participants will be about three hours for each of the 16,000 investment advisory firms.[82] The Department assumes that updating notices that are the same for all DC plan participants and beneficiaries is estimated to take on average one hour and a half for each of over 52,000 DC plans. The preparation time needed for individualized notices for IRAs is estimated to average 50 hours for each of 16,000 investment advisory firms. Thus the annual hour burden for preparation is estimated to be approximately 903,000 hours with an equivalent cost of approximately $98,829,000.

The Department assumes that all firms will outsource the creation of a computer program to enable them to prepare disclosures for IRA participants. This computer model will be used to generate disclosures to participants under both the statutory exemption and the class exemption. The Department estimates that a computer programmer will charge on average $1,200 per firm in the first year and $600 each subsequent year.[83] Thus the cost burden, given there are almost 16,000 investment advisory firms, will be approximately $18,662,000 in the first year and approximately $9,331,000 in all subsequent years.

Distribution of Statutory Exemption Disclosure Package

The Department assumes that a clerical professional will be required to spend one minute per page (four minutes per disclosure package) to photocopy the 20 percent of disclosure packages that are delivered in paper and one minute per disclosure package to prepare the ten percent of disclosures that are mailed each year.[84] These hours add up to an hour burden of approximately 864,000 hours; at a wage rate of approximately $21 for a clerical professional the equivalent cost is approximately $3,225,000.

The Department assumes that the paper and photocopy costs are five cents per page; thus, given that there are approximately 2,030,000 participants receiving paper disclosures, the associated cost burden for paper and photocopying under the statutory exemption is estimated to be $406,000 annually. Under the basic United States Postal Service postage at a cost of $0.42 [85] per disclosure package for approximately 1,015,000 participants receiving mailed disclosures, the postage costs are estimated at about $426,000 annually. Thus the cost burden associated with distributing disclosures to participants is $832,000 per year.

Independent Certification

If the fiduciary adviser provides the investment advice through use of a computer model, then before providing the advice, Section 2550.408g–1(d)(2) of the proposed regulation would require the fiduciary adviser to obtain the certification of an eligible investment expert as to the computer model's compliance with certain standards (*e.g.*, applies generally accepted investment theories, unbiased operation, objective criteria) set forth in the regulation. The Department assumes that there are six companies that will provide the investment advice computer model [86] and that legal professionals working at these six companies supply in-house support by providing documentation and other information to the eligible investment expert who certifies the company's investment advice computer model. These legal professionals are assumed to spend about 40 hours for each of the six investment advice computer model providers and on average 40 hours for each of the almost 16,000 investment advisory firms to whom the computer model providers supply their models. Thus, the investment advice computer model providers have an hour burden of approximately 622,000 hours for an equivalent cost of about $68,125,000.

The Department assumes that the investment advisory firm will need in-house legal professionals to provide documentation and other information to the eligible investment expert who certifies the investment advisory firm's investment advice computer model. These legal professionals will spend on average ten hours for each of over 52,000 DC plans and on average 50

[81] The following disclosures are assumed to be constant for all participants advised: The material affiliation or material contractual relationships, use of participant information, type of services provided by the fiduciary adviser, acknowledgment that the adviser is acting as a fiduciary of the DC plan or IRA, and a statement that the participant can arrange for advice from an adviser who does not receive fees in connection with the investment or has no material affiliation with the investments recommended. The following disclosures are assumed to be constant for each participant of an individual DC plan: The fees and compensation the adviser receives in connection with the suggested investments and the material affiliation to the suggested investments. As discussed below these last two disclosures are also the only disclosures that are specific to the IRA beneficiary, and as such will require the adviser to generate individual disclosures for each IRA beneficiary advised using the computer model generated by the service providers.

[82] The Department assumes that investment advisory firms will distribute the same disclosures throughout the year and that they only update their disclosure content for the annual disclosures. The Department further assumes that few disclosures are requested each year (one per firm on average) and most requested disclosures are distributed either electronically at a negligible cost or in person at small costs. The Department welcomes comments on these assumptions.

[83] The Department has based this cost estimate on limited industry data.

[84] Eighty percent of disclosures are assumed to be distributed electronically. In addition, the Department assumes that one half of all paper disclosures are delivered in person and one half are delivered through the mail.

[85] The USPS increased the cost of First Class Postage to $0.42 as of May 2008.

[86] Based on limited information with respect to the investment computer model industry, the Department estimates that there are six companies that produce investment advice computer models.

hours for each of the almost 16,000 investment advisory firms. Thus the hour burden in the first year for the certification of the investment advice computer model is approximately 1,924,000 hours with an equivalent cost of about $210,571,000.

The Department assumes that in subsequent years the hours required for any investment advice computer model recertification will be approximately half of the first certification and that investment advisory firms will have their investment advice computer model recertified on average once a year. Thus in the subsequent years the hour burden is approximately 962,000 hours with an equivalent cost of approximately $105,286,000.

Recordkeeping Requirements

Consistent with the statutory exemption, section 2550.408g–1(i) of the proposed regulation would require fiduciary advisers to maintain records with respect to the investment advice provided in reliance on the regulation necessary to determine whether the applicable requirements of the regulation have been satisfied. The Department assumes that all investment advisory firms maintain recordkeeping systems as part of their normal business practices. The Department assumes that all records that are required to be maintained will be kept electronically under normal business practices; therefore, no printing and negligible holding costs are anticipated to be associated with records maintenance.

Audit Requirement

Any fiduciary adviser relying on the exemption would be required to engage, at least annually, an independent auditor to conduct an audit of the investment advice arrangement for compliance with the conditions of the exemption pursuant to section 2550.408g–1(f)(1) of the proposed regulation. All firms are assumed to outsource this service but use some internal clerical and legal professional time to assist the auditor.[87] The clerical staff is expected to spend about three hours per advisory firm and on average ten minutes per participant to gather documentation and other information. The in-house legal professional is expected to need approximately four hours per advisory firm to assist the auditor with the statutory exemption audit. The Department estimates that about one percent of participants will be audited per year, resulting in approximately 101,000 audits. Overall, the annual in-house hour burden for the annual audit requirement is estimated at 126,000 hours, with equivalent costs of approximately $8,157,000.

The Department assumes that the statutory exemption audits will be outsourced to an independent legal professional for each of the almost 16,000 investment advisory firms and will cost on average $18,000.[88] Thus the annual cost burden will be approximately $279,936,000.

Summary of Statutory Exemption Hour and Cost Burden

In summary, the third-party disclosures, computer model certification, and audit requirements for the statutory exemption require approximately 3,981,000 burden hours with an equivalent cost of approximately $416,745,000 and a cost burden of approximately $579,367,000 in the first year. In each subsequent year the total labor burden hours are estimated to be approximately 2,143,000 hours with an equivalent cost of approximately $215,497,000 and the cost burden is estimated at approximately $430,067,000 per year.

The Class Exemption

The Department assumes that all of the 16,000 investment advisory firms that take advantage of the statutory exemption will also provide advice that relies on the class exemption. As mentioned above, all investment advisory firms provide advice under both DC plans and IRAs, and the number of investment advisory firms using this class exemptive relief is assumed to be constant over time. The Department estimates that under the class exemption approximately 52,000 DC retirement plans will seek to provide advice to their participants and beneficiaries. These plans represent approximately 6,611,000 participants and beneficiaries, of which approximately 2,016,000 will seek advice from the investment advisory firm employed on behalf of their employer sponsored retirement investment plan. IRAs can also make use of this class exemption, and the Department estimates that approximately 8.5 million IRA beneficiaries will seek advice under this class exemption.[89]

Disclosures to Participants

In general, section III(g)(1) of the Class Exemption requires a fiduciary adviser to furnish detailed information to a participant about an advice arrangement before initially providing investment advice, annually, upon participant request, and if there is any material change to the information. The information to be provided is the same under the class exemption as the statutory exemption (see Section I(a) above for a listing of all required disclosures). Additional disclosures required before providing investment advice would depend on which alternative conditions the arrangement is designed to satisfy. If the investment advice arrangement is based on the disclosure of computer-generated investment selections, the fiduciary adviser is required to furnish those selections to the participant. If the fiduciary adviser determines computer modeling of the number and types of investment choices available to an IRA is reasonably precluded, the fiduciary adviser may instead furnish asset class allocation models to the participant. Alternatively, such disclosures may not be required if a fiduciary adviser satisfies the condition that would require that the compensation of the person providing advice on behalf of the fiduciary adviser may not vary based on the particular investments selected. The Department assumes that investment advisory firms will compile all notices into a single five-page disclosure package for each participant given advice under the class exemption and that these disclosures will be prepared at the investment advisory firm, DC plan, and IRA beneficiary levels.

Preparation of Class Exemption Disclosure Package

The Department assumes that disclosures that are common to all of the advisory firm's client participants as well as the computer program used to

[87] Audit firms are expected to transmit the final audit report to the advisory firm through electronic means at no additional costs. The advisory firms must either furnish a copy of the audit report to IRA beneficiaries or make the audit report available on their Web site and inform IRA beneficiaries of the purpose of the report and how and where to locate the report applicable to their account with the other disclosures discussed above. The Department assumes that all advisory firms will make the audit report available on their Web site and add a few sentences to the single disclosure package at negligible costs. Any advisory firm whose audit report identifies noncompliance with the requirements of the statutory or class exemption must send a copy of the report to the Department within 30 days following receipt of the report. The Department assumes that the majority of advisory firms will comply with the exemption; therefore, the costs associated with sending the audit reports to the Department are expected to be negligible. The Department welcomes comments on this assumption.

[88] The Department has based this cost estimate on limited industry data.

[89] See footnote 51 above for an explanation of the number of entities affected by the regulation. The Department assumes that these DC plans are offering, and DC participants and beneficiaries, and IRA beneficiaries are receiving advice under the class exemption but not the statutory exemption.

generate disclosures to IRA beneficiaries will have been prepared to conform to the requirements of the statutory exemption and will not impose any additional burden on respondents.

For the first year disclosures, the Department assumes that the 16,000 investment advisory firms might require a legal professional to work on average 80 hours each to assist an out-sourced computer programmer in creating computer software that will generate individualized disclosure notices for IRA participants, and approximately two hours per DC plan to prepare disclosures that are common to all participants in the same DC plan. These hours add up to an hour burden of approximately 1,349,000 hours; at a wage rate of $109 for a legal professional the equivalent cost is approximately $147,662,000.

For the annual updating of disclosures the Department assumes that the preparation time needed for updating the notices will be on average one hour per DC plan (for DC plan individualized disclosures) and on average 40 hours for each investment advisory firms (for IRA beneficiary individualized disclosures). Thus, the annual hour burden is estimated to be approximately 674,000 with an equivalent cost of approximately $73,831,000.

Distribution of Class Exemption Disclosure Package

The Department assumes that a clerical professional will spend five minutes [90] to photocopy each of the approximately 2,102,000 disclosure packages that are delivered in paper and one minute to prepare each of the 1,051,000 disclosures that are mailed each year. These hours add up to an hour burden of approximately 193,000 hours; at a wage rate of $21 for a clerical professional the equivalent cost is approximately $4,082,000.

Using a paper and photocopy cost of five cents per page, the associated cost burden for paper and photocopying under the class exemption is estimated to be $525,000 annually. Under the basic USPS postage at a cost of $0.42 per disclosure package, the cost burden of the mailing disclosures under the class exemption will be approximately $441,000 annually. Thus the overall cost burden associated with distributing disclosures to participants is estimated at about $967,000 per year.

Independent Certification

The entire costs of the certification requirements are accounted for under the statutory exemption.

Policies and Procedures

Section III(i) of the Class Exemption requires investment advisory firms that wish to provide investment advice pursuant to the class exemption to develop written policies and procedures that insure the firm follows all of the class exemption requirements. The Department estimates that updating the written policies and procedures will generally require no additional costs. It is assumed that the preparation of these policies and procedures will require on average seven hours of legal professional time for each of the almost 16,000 investment advisory firms. This leads to an hour burden in the first year of about 109,000 hours with an equivalent cost of approximately $11,917,000.

Recordkeeping Requirements

Section III(n) of the proposed class exemption requires fiduciary advisers to maintain records with respect to the investment advice provided in reliance on the exemption necessary to determine, explain or verify compliance with the conditions of the exemption, including those records necessary to determine that the disclosures described above have been made. In this connection, the fiduciary adviser would be required to maintain records necessary to determine, among other things, that an independent fiduciary has provided express authorization of the arrangement under which the investment advice is provided, that, if applicable, an eligible investment expert has provided the requisite certification, that the compensation to the fiduciary adviser and its affiliates in connection with the investments is reasonable, that the terms of the purchase sale or holding of the investment are at least as favorable to the plan or IRA as those in an arm's length transactions would be, and in cases where the advice is not provided after disclosure of computer generated investments or an asset class allocation model, the fees or other compensation received by an employee, agent or registered representative providing investment advice on behalf of the fiduciary adviser does not vary depending on the option. The Department assumes that all investment advisory firms maintain recordkeeping systems to satisfy these information collections requirements.

A fiduciary adviser may provide individualized investment advice to participants or beneficiaries (''off-model advice'') following the furnishing of investment advice generated by a computer model as described in section III(e)(1) of the Class Exemption, or in the case of beneficiaries of IRAs described in section III(e)(2), following the furnishing of investment education-type materials (graphs, pie charts, etc) that produce or reflect asset allocation models. However, section III(e)(4) of the Class Exemption requires that, with respect to any off-model advice that recommends investment options that may generate for the adviser or certain other parties greater income than other investments in the same asset class, the individual who provides investment advice on behalf of the fiduciary adviser, not later than 30 days after providing the advice, must document the basis for concluding that the recommendation is in the best interest of the participant or beneficiary. The Department assumes that such off -model advice will be provided in ten percent of the possible DC plan cases, and 30 percent of the possible IRA beneficiary cases. Thus, of the approximately 2,016,000 DC participants and approximately 8.5 million IRA beneficiaries receiving advice under the class exemption, almost 202,000 DC plan participants and 2.5 million IRA beneficiaries will receive off-model advice.[91]

The Department further assumes that each participant receiving advice will receive this advice an average of four times per year (once a quarter), resulting in almost 10,996,000 reports. The Department assumes that each investment advisor who provides off-model advice will need approximately 15 minutes to write this report. Generating these reports is estimated to result in approximately 2,749,000 annual burden hours for the financial manager with an associated equivalent cost of $217,125,000.

Audit

Any fiduciary adviser relying on the class exemption also would be required to engage, at least annually, an independent auditor to conduct an audit of the investment advice arrangement for compliance with the class exemption and written policies and procedures (as described below) designed to assure

[90] The Department estimates that most of the investment advisory firms that take advantage of the class exemption will determine that computer modeling of the number and types of investment choices available to an IRA is not possible, and will instead furnish asset class allocation models to the beneficiaries. As such, the disclosure package for participants who receive advice pursuant to the class exemption is estimated as being five pages in length, instead of four.

[91] Based on limited information on the type of advice given to participants, the Department estimates that ten percent of DC plan participants and 30 percent of IRA beneficiaries will receive off-Model Advice.

compliance with the conditions of the exemption. The fiduciary adviser would be required to issue a written report to each plan fiduciary who authorized the use of the investment advice arrangement, and to IRA beneficiaries, setting forth the auditor's findings. With respect to IRA's, the fiduciary adviser may instead make the report available on its Web site. Also with respect to an arrangement with an IRA, if the auditor finds noncompliance with the exemption, the fiduciary adviser must file the report with the Department of Labor.

All firms are assumed to outsource this service but use some internal clerical and legal professional time to assist the auditor. As an audit is required under the statutory exemption, the fixed in-house hours are attributed to the statutory exemption and only the variable clerical hours are divided between the statutory and class exemption. Under the class exemption clerical staff is expected to spend on average ten minutes per audited participant to pull each audited participant's files or to provide other documentation or information. The Department estimates that about 105,000 participants will be audited annually. Overall, the annual in-house hour burden for the audit requirement is estimated at 18,000 hours with equivalent costs of approximately $371,000.

The Department assumes that the class exemption audits will be outsourced to an independent legal professional for each of the almost 16,000 investment advisory firms and will cost on average $4,000 per year for each investment advisory firm.[92] Thus the annual cost burden will be approximately $62,208,000.

Summary of Class Exemption Hour and Cost Burden

In summary, the third-party disclosures, written policies and procedures, recordkeeping and audit requirements for the class exemption are estimated to require a total of approximately 4,417,000 burden hours with an equivalent cost of approximately $381,157,000 and a total cost burden of approximately $63,175,000 in the first year. In each subsequent year the total burden hours are estimated at approximately 3,634,000 hours with an equivalent cost of approximately $295,409,000 and a total cost burden of approximately $63,175,000 per year.

[92] The Department has based this cost estimate on limited industry data.

Overall Exemption Hour and Cost Burden Summary

In summary, the third-party disclosures, computer model certification, written policies and procedures, recordkeeping and audit requirements for the statutory and class exemptions require approximately 8,398,000 burden hours with an equivalent cost of approximately $797,903,000 and a cost burden of approximately $642,541,000 in the first year. The labor burden hours in each subsequent year are approximately 5,776,000 hours with an equivalent cost of approximately $510,906,000 and the cost burden in each subsequent year is approximately $493,242,000 per year.

These paperwork burden estimates are summarized as follows:

Type of Review: New collection (Request for new OMB Control Number).

Agency: Employee Benefits Security Administration, Department of Labor.

Titles: (1) Proposed Class Exemption for the Provision of Investment Advice to Participants and Beneficiaries of Self-Directed Individual Account Plans and IRAs and (2) Proposed Investment Advice Regulation.

OMB Control Number: 1210–NEW.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 16,000.

Estimated Number of Annual Responses: 20,656,000.

Frequency of Response: Initially, Annually, Upon Request, when a material change.

Estimated Total Annual Burden Hours: 8,398,000 hours in the first year; 5,776,000 hours in each subsequent year.

Estimated Total Annual Burden Cost: $642,541,000 for the first year; $493,242,000 for each subsequent year.

List of Subjects in 29 CFR Part 2550

Employee benefit plans, Exemptions, Fiduciaries, Investments, Pensions, Prohibited transactions, Reporting and recordkeeping requirements, and Securities.

For the reasons set forth in the preamble, the Department proposes to amend Chapter XXV, subchapter F, part 2550 of Title 29 of the Code of Federal Regulations as follows:

Subchapter F—Fiduciary Responsibility Under the Employee Retirement Income Security Act of 1974

PART 2550—RULES AND REGULATIONS FOR FIDUCIARY RESPONSIBILITY

1. The authority citation for part 2550 is revised to read as follows:

Authority: 29 U.S.C. 1135; and Secretary of Labor's Order No. 1–2003, 68 FR 5374 (Feb. 3, 2003). Sec. 2550.401b–1 also issued under sec. 102, Reorganization Plan No. 4 of 1978, 43 FR 47713 (Oct. 17, 1978), 3 CFR, 1978 Comp. 332, effective Dec. 31, 1978, 44 FR 1065 (Jan. 3, 1978), 3 CFR, 1978 Comp. 332. Sec. 2550.401c–1 also issued under 29 U.S.C. 1101. Sec. 2550.404c–1 also issued under 29 U.S.C. 1104. Sec. 2550.407c–3 also issued under 29 U.S.C. 1107. Sec. 2550.404a–2 also issued under 26 U.S.C. 401 note (sec. 657, Pub. L. 107–16, 115 Stat. 38). Sec. 2550.408b–1 also issued under 29 U.S.C. 1108(b)(1) and sec. 102, Reorganization Plan No. 4 of 1978, 3 CFR, 1978 Comp. p. 332, effective Dec. 31, 1978, 44 FR 1065 (Jan. 3, 1978), and 3 CFR, 1978 Comp. 332. Sec. 2550.412–1 also issued under 29 U.S.C. 1112.

2. Add § 2550.408g–1 to read as follows:

§ 2550.408g–1 Investment Advice—Participants and Beneficiaries.

(a) *General.* Section 408(g)(1) of the Employee Retirement Income Security Act, as amended (ERISA), provides an exemption from the prohibitions of section 406 of ERISA for transactions described in section 408(b)(14) of ERISA in connection with the provision of investment advice to a participant or a beneficiary if the investment advice is provided by a fiduciary adviser under an ''eligible investment advice arrangement.'' Section 4975(d)(17) and (f)(8) of the Internal Revenue Code, as amended (the Code), contain parallel provisions to ERISA section 408(b)(14) and (g)(1).

(b) *Eligible investment advice arrangement.* For purposes of section 408(g)(1) of ERISA and section 4975(f)(8) of the Code, an ''eligible investment advice arrangement'' means an arrangement that meets either the requirements of paragraph (c) of this section or paragraph (d) of this section, or both.

(c) *Arrangements that use fee-leveling.* For purposes of this section, an arrangement is an eligible investment advice arrangement if—

(1)(i) Any investment advice is based on generally accepted investment theories that take into account the historic returns of different asset classes over defined periods of time, although nothing herein shall preclude any investment advice from being based on generally accepted investment theories

that take into account additional considerations;

(ii) Any investment advice takes into account information furnished by a participant or beneficiary relating to age, life expectancy, retirement age, risk tolerance, other assets or sources of income, and investment preferences, although nothing herein shall preclude any investment advice from taking into account additional information that a participant or beneficiary may provide;

(iii) Any fees or other compensation (including salary, bonuses, awards, promotions, commissions or other things of value) received, directly or indirectly, by any employee, agent or registered representative that provides investment advice on behalf of a fiduciary adviser does not vary depending on the basis of any investment option selected by a participant or beneficiary;

(iv) Any fees (including any commission or other compensation) received by the fiduciary adviser for investment advice or with respect to the sale, holding, or acquisition of any security or other property for purposes of investment of plan assets do not vary depending on the basis of any investment option selected by a participant or beneficiary; and

(2) The requirements of paragraphs (e), (f), (g), (h), and (i) of this section are met.

(d) *Arrangements that use computer models.* For purposes of this section, an arrangement is an eligible investment advice arrangement if the only investment advice provided under the arrangement is advice that is generated by a computer model described in paragraphs (d)(1) and (2) of this section under an investment advice program and with respect to which the requirements of paragraphs (e), (f), (g), (h), and (i) are met, and any acquisition, holding or sale of a security or other property pursuant to such advice occurs solely at the direction of the participant or beneficiary.

(1) A computer model shall be designed and operated to—

(i) Apply generally accepted investment theories that take into account the historic returns of different asset classes over defined periods of time, although nothing herein shall preclude a computer model from applying generally accepted investment theories that take into account additional considerations;

(ii) Utilize information furnished by a participant or beneficiary relating to age, life expectancy, retirement age, risk tolerance, other assets or sources of income, and investment preferences, although nothing herein shall preclude a computer model from taking into account additional information that a plan or a participant or beneficiary may provide;

(iii) Utilize appropriate objective criteria to provide asset allocation portfolios comprised of investment options available under the plan;

(iv) Avoid investment recommendations that:

(A) Inappropriately favor investment options offered by the fiduciary adviser or a person with a material affiliation or material contractual relationship with the fiduciary adviser over other investment options, if any, available under the plan; or

(B) Inappropriately favor investment options that may generate greater income for the fiduciary adviser or a person with a material affiliation or material contractual relationship with the fiduciary adviser;

(v) Take into account all designated investment options, within the meaning of paragraph (j)(1) of this section, available under the plan without giving inappropriate weight to any investment option; except that a computer model shall not be treated as failing to meet this requirement merely because it does not take into account an investment option that constitutes an investment primarily in qualifying employer securities.

(2) Prior to utilization of the computer model, the fiduciary adviser shall obtain a written certification, meeting the requirements of paragraph (d)(4) of this section from an eligible investment expert, within the meaning of paragraph (d)(3) of this section, that the computer model meets the requirements of paragraph (d)(1) of this section. If, following a certification, a computer model is modified in a manner that may affect its ability to meet the requirements of paragraph (d)(1), the fiduciary adviser shall, prior to utilization of the modified model, obtain a new certification from an eligible investment expert that the computer model, as modified, meets the requirements of paragraph (d)(1).

(3) The term ''eligible investment expert'' means a person that, through employees or otherwise, has the appropriate technical training or experience and proficiency to analyze, determine and certify, in a manner consistent with paragraph (d)(4) of this section, whether a computer model meets the requirements of paragraph (d)(1) of this section; except that the term ''eligible investment expert'' does not include any person that has any material affiliation or material contractual relationship with the fiduciary adviser, with a person with a material affiliation or material contractual relationship with the fiduciary adviser, or with any employee, agent, or registered representative of the foregoing.

(4) A certification by an eligible investment expert shall—

(i) Be in writing;

(ii) Contain—

(A) An identification of the methodology or methodologies applied in determining whether the computer model meets the requirements of paragraph (d)(1) of this section;

(B) An explanation of how the applied methodology or methodologies demonstrated that the computer model met the requirements of paragraph (d)(1) of this section;

(C) A description of any limitations that were imposed by any person on the eligible investment expert's selection or application of methodologies for determining whether the computer model meets the requirements of paragraph (d)(1) of this section;

(D) A representation that the methodology or methodologies were applied by a person or persons with the educational background, technical training or experience necessary to analyze and determine whether the computer model meets the requirements of paragraph (d)(1);

(E) A statement certifying that the eligible investment expert has determined that the computer model meets the requirements of paragraph (d)(1) of this section; and

(iii) Be signed by the eligible investment expert.

(5) The selection of an eligible investment expert as required by this section is a fiduciary act governed by section 404(a)(1) of ERISA.

(e) *Arrangement must be authorized by a plan fiduciary.* The arrangement pursuant to which investment advice is provided to participants and beneficiaries pursuant to this section must be expressly authorized by a plan fiduciary (or, in the case of an Individual Retirement Account (IRA), the IRA beneficiary) other than: the person offering the arrangement; any person providing designated investment options under the plan; or any affiliate of either. Provided, however, that for purposes of the preceding, in the case of an IRA, an IRA beneficiary will not be treated as an affiliate of a person solely by reason of being an employee of such person.

(f) *Annual audit.* (1) The fiduciary adviser shall, at least annually, engage an independent auditor, who has appropriate technical training or experience and proficiency, and so

represents in writing to the fiduciary adviser, to:

(i) Conduct an audit of the investment advice arrangements for compliance with the requirements of this section; and

(ii) Within 60 days following completion of the audit, issue a written report to the fiduciary adviser and, except with respect to an arrangement with an IRA, to each fiduciary who authorized the use of the investment advice arrangement, consistent with paragraph (e) of this section, setting forth the specific findings of the auditor regarding compliance of the arrangement with the requirements of this section.

(2) With respect to an arrangement with an IRA, the fiduciary adviser:

(i) Within 30 days following receipt of the report from the auditor, as described in paragraph (f)(1)(ii) of this section, shall furnish a copy of the report to the IRA beneficiary or make such report available on its website, provided that such beneficiaries are provided information, with the information required to be disclosed pursuant to paragraph (g) of this section, concerning the purpose of the report, and how and where to locate the report applicable to their account; and

(ii) In the event that the report of the auditor identifies noncompliance with the requirements of this section, within 30 days following receipt of the report from the auditor, shall send a copy of the report to the Department of Labor at the following address: Investment Advice Exemption Notification—Statutory, U.S. Department of Labor, Employee Benefits Security Administration, Room N–1513, 200 Constitution Ave., NW., Washington, DC, 20210.

(3) For purposes of this paragraph (f), an auditor is considered independent if it does not have a material affiliation or material contractual relationship with the person offering the investment advice arrangement to the plan or any designated investment options under the plan.

(4) For purposes of this paragraph (f), the auditor shall review sufficient relevant information to formulate an opinion as to whether the investment advice arrangements, and the advice provided pursuant thereto, offered by the fiduciary adviser during the audit period were in compliance with this section. Nothing in this paragraph shall preclude an auditor from using information obtained by sampling, as reasonably determined appropriate by the auditor, investment advice arrangements, and the advice pursuant thereto, during the audit period.

(g) *Disclosure.* (1) The fiduciary adviser must provide, without charge, to a participant or a beneficiary before the initial provision of investment advice with regard to any security or other property offered as an investment option, a written notification—

(i) Of the role of any party that has a material affiliation or material contractual relationship with the fiduciary adviser in the development of the investment advice program, and in the selection of investment options available under the plan;

(ii) Of the past performance and historical rates of return of the designated investment options available under the plan, to the extent that such information is not otherwise provided;

(iii) Of all fees or other compensation relating to the advice that the fiduciary adviser or any affiliate thereof is to receive (including compensation provided by any third party) in connection with the provision of the advice or in connection with the sale, acquisition, or holding of the security or other property;

(iv) Of any material affiliation or material contractual relationship of the fiduciary adviser or affiliates thereof in the security or other property;

(v) Of the manner, and under what circumstances, any participant or beneficiary information provided under the arrangement will be used or disclosed;

(vi) Of the types of services provided by the fiduciary adviser in connection with the provision of investment advice by the fiduciary adviser, including, with respect to a computer model arrangement referred to in paragraph (d) of this section, any limitations on the ability of a computer model to take into account an investment option that constitutes an investment primarily in qualifying employer securities, as provided for in paragraph (d)(1)(v) of this section;

(vii) That the adviser is acting as a fiduciary of the plan in connection with the provision of the advice; and

(viii) That a recipient of the advice may separately arrange for the provision of advice by another adviser that could have no material affiliation with and receive no fees or other compensation in connection with the security or other property.

(2)(i) The notification required under paragraph (g)(1) of this section must be written in a clear and conspicuous manner and in a manner calculated to be understood by the average plan participant and must be sufficiently accurate and comprehensive to reasonably apprise such participants and beneficiaries of the information required to be provided in the notification.

(ii) The appendix to this section contains a model disclosure form that may be used to provide notification of the information described in paragraph (g)(1)(iii) of this section. Use of the model form is not mandatory. However, use of an appropriately completed model disclosure form will be deemed to satisfy the requirement of paragraphs (g)(1) and (2)(i) of this section with respect to such information.

(3) The notification required under paragraph (g)(1) of this section may, in accordance with 29 CFR 2520.104b–1, be provided in written or electronic form.

(4) At all times during the provision of advisory services to the participant or beneficiary pursuant to the arrangement, the fiduciary adviser must—

(i) Maintain the information described in paragraph (g)(1) of this section in accurate form and in the manner described in paragraph (g)(2) of this section,

(ii) Provide, without charge, accurate information to the recipient of the advice no less frequently than annually,

(iii) Provide, without charge, accurate information to the recipient of the advice upon request of the recipient, and

(iv) Provide, without charge, accurate information to the recipient of the advice concerning any material change to the information required to be provided to the recipient of the advice at a time reasonably contemporaneous to the change in information.

(h) *Other Conditions.* The requirements of this paragraph are met if—

(1) The fiduciary adviser provides appropriate disclosure, in connection with the sale, acquisition, or holding of the security or other property, in accordance with all applicable securities laws,

(2) The sale, acquisition, or holding occurs solely at the direction of the recipient of the advice,

(3) The compensation received by the fiduciary adviser and affiliates thereof in connection with the sale, acquisition, or holding of the security or other property is reasonable, and

(4) The terms of the sale, acquisition, or holding of the security or other property are at least as favorable to the plan as an arm's length transaction would be.

(i) *Maintenance of Records.*—The fiduciary adviser must maintain, for a period of not less than 6 years after the provision of investment advice pursuant to the arrangement, any records necessary for determining whether the

applicable requirements of this section have been met. A transaction prohibited under section 406 of ERISA shall not be considered to have occurred solely because the records are lost or destroyed prior to the end of the 6-year period due to circumstances beyond the control of the fiduciary adviser.

(j) *Definitions.* For purposes of this section:

(1) The term ''designated investment option'' means any investment option designated by the plan into which participants and beneficiaries may direct the investment of assets held in, or contributed to, their individual accounts. The term ''designated investment option'' shall not include ''brokerage windows,'' ''self-directed brokerage accounts,'' or similar plan arrangements that enable participants and beneficiaries to select investments beyond those designated by the plan.

(2) The term ''fiduciary adviser'' means, with respect to a plan, a person who is a fiduciary of the plan by reason of the provision of investment advice referred to in section 3(21)(A)(ii) of ERISA by the person to the participant or beneficiary of the plan and who is—

(i) Registered as an investment adviser under the Investment Advisers Act of 1940 (15 U.S.C. 80b–1 *et seq.*) or under the laws of the State in which the fiduciary maintains its principal office and place of business,

(ii) A bank or similar financial institution referred to in section 408(b)(4) of ERISA or a savings association (as defined in section 3(b)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1813(b)(1)), but only if the advice is provided through a trust department of the bank or similar financial institution or savings association which is subject to periodic examination and review by Federal or State banking authorities,

(iii) An insurance company qualified to do business under the laws of a State,

(iv) A person registered as a broker or dealer under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*),

(v) An affiliate of a person described in any of clauses (i) through (iv), or

(vi) An employee, agent, or registered representative of a person described in paragraphs (j)(2)(i) through (v) of this section who satisfies the requirements of applicable insurance, banking, and securities laws relating to the provision of advice.

(vii) Except as provided under 29 CFR 2550.408g–2, a fiduciary adviser includes any person who develops the computer model, or markets the computer model or investment advice program, utilized in satisfaction of paragraph (d) of this section.

(3) A ''registered representative'' of another entity means a person described in section 3(a)(18) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(18)) (substituting the entity for the broker or dealer referred to in such section) or a person described in section 202(a)(17) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–2(a)(17)) (substituting the entity for the investment adviser referred to in such section).

(4) ''Individual Retirement Account'' or ''IRA'' means—

(i) An individual retirement account described in section 408(a) of the Code;

(ii) An individual retirement annuity described in section 408(b) of the Code;

(iii) An Archer MSA described in section 220(d) of the Code;

(iv) A health savings account described in section 223(d) of the Code;

(v) A Coverdell education savings account described in section 530 of the Code; or

(vi) A trust, plan, account, or annuity which, at any time, has been determined by the Secretary of the Treasury to be described in any of paragraphs (j)(4)(i) through (v) of this section.

(5) An ''affiliate'' of another person means—

(i) Any person directly or indirectly owning, controlling, or holding with power to vote, 5 percent or more of the outstanding voting securities of such other person;

(ii) Any person 5 percent or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such other person;

(iii) Any person directly or indirectly controlling, controlled by, or under common control with, such other person; and

(iv) Any officer, director, partner, copartner, or employee of such other person.

(6)(i) A person with a ''material affiliation'' with another person means—

(A) Any affiliate of the other person;

(B) Any person directly or indirectly owning, controlling, or holding, 5 percent or more of the interests of such other person;

(C) Any person 5 percent or more of whose interests are directly or indirectly owned, controlled, or held, by such other person.

(ii) For purposes of paragraph (j)(6)(i) of this section, ''interest'' means with respect to an entity—

(A) The combined voting power of all classes of stock entitled to vote or the total value of the shares of all classes of stock of the entity if the entity is a corporation;

(B) The capital interest or the profits interest of the entity if the entity is a partnership; or

(C) The beneficial interest of the entity if the entity is a trust or unincorporated enterprise.

(7) Persons have a ''material contractual relationship'' if payments made by one person to the other person pursuant to written contracts or agreements between the persons exceed 10 percent of the gross revenue, on an annual basis, of such other person.

(8) ''Control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

Appendix to § 2550.408g–1

Fiduciary Adviser Disclosure

This document contains important information about [*enter name of* Fiduciary Adviser] and how it is compensated for the investment advice provided to you. You should carefully consider this information in your evaluation of that advice.

[*enter name of* Fiduciary Adviser] has been selected to provide investment advisory services for the [*enter name of* Plan]. [*enter name of* Fiduciary Adviser] will be providing these services as a fiduciary under the Employee Retirement Income Security Act (ERISA). [*enter name of* Fiduciary Adviser], therefore, must act prudently and with only your interest in mind when providing you recommendations on how to invest your retirement assets.

Compensation of the Fiduciary Advisor and Related Parties

[*enter name of* Fiduciary Adviser] (is/is not) compensated by the plan for the advice it provides. (*if compensated by the plan, explain what and how compensation is charged (e.g., asset-based fee, flat fee, per advice)). (If applicable,* [*enter name of* Fiduciary Adviser] is not compensated on the basis of the investment(s) selected by you.)

Affiliates of [*enter name of* Fiduciary Adviser] (*if applicable enter,* and other parties with whom [enter name of Fiduciary Adviser] has a material affiliation or material contractual relationship [93]) also will be providing services for which they will be compensated. These services include: [*enter description of services, e.g., investment management, transfer agent, custodial, and shareholder services for some/all the investment funds available under the plan.*]

When [*enter name of* Fiduciary Adviser] recommends that you invest your assets in an investment fund of its own or one of its affiliates and you follow that advice, [*enter name of* Fiduciary Adviser] or that affiliate will receive compensation from the investment fund based on the amount you invest. The amounts that will be paid by you will vary depending on the particular fund in which you invest your assets and may range from __% to __%. Specific information

[93] See 29 CFR 2550.408g–1.

concerning the fees and other charges of each investment fund is available from [*enter source, such as: Your plan administrator, investment fund provider (possibly with Internet Web site address)*]. This information should be reviewed carefully before you make an investment decision.

(*if applicable enter,* [*enter name of* Fiduciary Adviser] or affiliates of [*enter name of* Fiduciary Adviser] also receive compensation from non-affiliated investment funds as a result of investments you make as a result of recommendations of [*enter name of* Fiduciary Adviser]. The amount of this compensation also may vary depending on the particular fund in which you invest. This compensation may range from __% to __%. Specific information concerning the fees and other charges of each investment fund is available from [*enter source, such as: Your plan administrator, investment fund provider (possibly with Internet Web site address)*]. This information should be reviewed carefully before you make an investment decision.

(*if applicable enter,* In addition to the above, [*enter name of* Fiduciary Adviser] or affiliates of [*enter name of* Fiduciary Adviser] also receive other fees or compensation, such as commissions, in connection with the sale, acquisition of holding of investments selected by you as a result of recommendations of [*enter name of* Fiduciary Adviser]. These amounts are: [*enter description of all other fees or compensation to be received in connection with sale, acquisition or holding of investments*]. This information should be reviewed carefully before you make an investment decision.

Investment Returns

While understanding investment-related fees and expenses is important in making informed investment decisions, it is also important to consider additional information about your investment options, such as performance, investment strategies and risks. Specific information related to the past performance and historical rates of return of the investment options available under the plan (has/has not) been provided to you by [*enter source, such as: Your plan administrator, investment fund provider*]. (*if applicable enter,* If not provided to you, the information is attached to this document.)

For options with returns that vary over time, past performance does not guarantee how your investment in the option will perform in the future; your investment in these options could lose money.

Parties Participating in Development of Advice Program or Selection of Investment Options

Name, and describe role of, affiliates or other parties with whom the fiduciary adviser has a material affiliation or contractual relationship that participated in the development of the investment advice program (if this is an arrangement that uses computer models) or the selection of investment options available under the plan.

Use of Personal Information

Include a brief explanation of the following—

What personal information will be collected;

How the information will be used;

Parties with whom information will be shared;

How the information will be protected; and

When and how notice of the Fiduciary Adviser's privacy statement will be available to participants and beneficiaries.

Consider Impact of Compensation on Advice

The fees and other compensation that [*enter name of* Fiduciary Adviser] and its affiliates receive on account of assets in [*enter name of* Fiduciary Adviser] (*enter if applicable,* and non-[*enter name of* Fiduciary Adviser]) investment funds are a significant source of revenue for the [*enter name of* Fiduciary Adviser] and its affiliates. You should carefully consider the impact of any such fees and compensation in your evaluation of the investment that [*enter name of* Fiduciary Adviser] provides to you. In this regard, you may arrange for the provision of advice by another adviser that may have not material affiliation with or receive compensation in connection with the investment funds or products offered under the plan. This type of advice is/is not available through your plan.

Should you have any questions about [*enter name of* Fiduciary Adviser] or the information contained in this document, you may contact [*enter name of contact person for fiduciary adviser, telephone number, address*].

3. Add § 2550.408g–2 to read as follows:

§ 2550.408g–2 Investment advice—fiduciary election.

(a) *General.* Section 408(g)(11)(A) of the Employee Retirement Income Security Act, as amended (ERISA), provides that a person who develops a computer model or who markets a computer model or investment advice program used in an ''eligible investment advice arrangement'' shall be treated as a fiduciary of a plan by reason of the provision of investment advice referred to in ERISA section 3(21)(A)(ii) to the plan participant or beneficiary, and shall be treated as a ''fiduciary adviser'' for purposes of ERISA section 408(b)(14) and (g). Section 4975(f)(8) of the Internal Revenue Code, as amended (the Code), contains a parallel provision to ERISA section 408(g)(11). This section sets forth requirements that must be satisfied in order for one such fiduciary adviser to elect to be treated as a fiduciary with respect to a plan under an eligible investment advice arrangement.

(b)(1) If an election meets the requirements in paragraph (b)(2) of this section, then the person identified in the election shall be the sole fiduciary adviser treated as a fiduciary by reason of developing or marketing the computer model, or marketing the investment advice program, used in an eligible investment advice arrangement.

(2) An election satisfies the requirements of this subparagraph with respect to an eligible investment advice arrangement if the election is in writing and such writing—

(i) Identifies the investment advice arrangement, and the person offering the arrangement, with respect to which the election is to be effective;

(ii) Identifies a person who—

(A) Is described in any of 29 CFR 2550.408g–1(j)(2) (i) through (v),

(B) Develops the computer model, or markets the computer model or investment advice program, utilized in satisfaction of 29 CFR 2550.408g–1(d) with respect to the arrangement, and

(C) Acknowledges that it elects to be treated as the only fiduciary, and fiduciary adviser, by reason of developing such computer model, or marketing such computer model or investment advice program;

(iii) Is signed by the person identified in paragraph (b)(2)(ii) of this section;

(iv) Is furnished to the fiduciary who authorized the arrangement, in accordance with 29 CFR 2550.408g–1(e); and

(v) Is maintained in accordance with 29 CFR 2550.408g–1(i).

Signed at Washington, DC, this 15th day of August, 2008.

Bradford P. Campbell,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

[FR Doc. E8–19272 Filed 8–21–08; 8:45 am]

BILLING CODE 4510–29–P

Notices

Federal Register
Vol. 73, No. 164
Friday, August 22, 2008

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

RIN 1210–ZA14

Proposed Class Exemption for the Provision of Investment Advice to Participants and Beneficiaries of Self-Directed Individual Account Plans and IRAs

AGENCY: Employee Benefits Security Administration, DOL.

ACTION: Notice of proposed class exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (Department) of a proposed class exemption from certain prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974, as amended (ERISA, or the Act), and from certain taxes imposed by the Internal Revenue Code of 1986, as amended (Code). If granted, the proposed exemption would permit the provision of investment advice described in section 3(21)(A)(ii) of the Act by a fiduciary adviser to a participant or beneficiary in an individual account plan or individual retirement accounts (and certain similar plans), the acquisition, holding or sale of a security or other property pursuant to the investment advice, and the direct or indirect receipt of fees or other compensation by the fiduciary adviser (or any employee, agent, registered representative or affiliate thereof) in connection with such transactions. The proposed exemption, if granted, would affect sponsors, fiduciaries, participants and beneficiaries of participant-directed individual account plans, as well as providers of investments and investment advice-related services to such plans.

DATES: Written comments on the proposed exemption should be submitted to the Department of Labor on or before October 6, 2008.

ADDRESSES: To facilitate the receipt and processing of comment letters, the Employee Benefits Security Administration (EBSA) encourages interested persons to submit their comments electronically by e-mail to *e-ORI@dol.gov* (Subject: Investment Advice Class Exemption), or by using the Federal eRulemaking portal at *http://www.regulations.gov* (follow instructions for submission of comments). Persons submitting comments electronically are encouraged not to submit paper copies. Persons interested in submitting paper copies should send or deliver their comments to the Office of Regulations and Interpretations, Employee Benefits Security Administration, Attn: Investment Advice Class Exemption, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. All comments will be available to the public, without charge, online at *http://www.regulations.gov* and *http://www.dol.gov/ebsa* and at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Fred Wong, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll free number.

SUPPLEMENTARY INFORMATION: This document contains a notice of pendency before the Department of a proposed class exemption from the restrictions of section 406(a) and 406(b) of the Act and from the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code. The Department is proposing this class exemption pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, August 10, 1990).[1] All section references herein are to sections of ERISA unless otherwise indicated.

A. Background

Section 3(21)(A)(ii) of the Act includes within the definition of ''fiduciary'' a person that renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys of other property of a plan, or has any authority or responsibility to do so.[2] The prohibited transaction provisions of ERISA and the Code prohibit an investment advice fiduciary from using the authority, control or responsibility that makes it a fiduciary to cause itself, or a party in which it has an interest that may affect its best judgment as a fiduciary, to receive additional fees. As a result, in the absence of a statutory or administrative exemption, fiduciaries are prohibited from rendering investment advice to plan participants regarding investments that result in the payment of additional advisory and other fees to the fiduciaries or their affiliates.

With the growth of participant-directed individual account plans, there has been an increasing recognition of the importance of investment advice to participants and beneficiaries in such plans. Most recently, Congress and the Administration, responding to the need to afford participants and beneficiaries greater access to professional investment advice, amended the prohibited transaction provisions of ERISA and the Code, as part of the Pension Protection Act of 2006 (PPA),[3] to permit a broader array of investment advice providers to offer their services to participants and beneficiaries responsible for investment of assets in their individual accounts and, accordingly, for the adequacy of their retirement savings. Specifically, section 601(a) of the PPA added a statutory exemption under sections 408(b)(14) and 408(g) of ERISA. Parallel provisions were added to the Code at section 4975(d)(17) and 4975(f)(8).[4]

[1] Section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), generally transferred the authority of the Secretary of the Treasury to issue exemptions under section 4975(c)(2) of the Code to the Secretary of Labor. For purposes of this proposed exemption, references to specific provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

[2] *See also* 29 CFR 2510.3–21(c).

[3] Public Law 109–280, 120 Stat. 780 (Aug. 17, 2006).

[4] *See* PPA section 601(b). Under Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978), 5 U.S.C. App.1, 92 Stat. 3790, the authority of the Secretary of the Treasury to issue rulings under section 4975 of the Code has been transferred, with certain exceptions not here relevant, to the Secretary of Labor. Therefore, the references in this

Section 408(b)(14) of ERISA provides that certain investment advice-related transactions will be exempt from the prohibitions of section 406 if the requirements of section 408(g) are met. Section 408(g) of ERISA requires that investment advice must be provided by a fiduciary adviser under an ''eligible investment advice arrangement'' that meets a ''level fee'' requirement (ERISA section 408(g)(2)(A)(i)) or a ''computer model'' requirement (ERISA section 408(g)(2)(A)(ii)). However, PPA section 601(b)(3)(C) restricts the general availability of an eligible investment advice arrangement based on utilization of a computer model for certain plans described in Code section 4975(e)(1) (collectively referred to herein as Individual Retirement Accounts or IRAs), unless the Secretary of Labor, in consultation with the Secretary of the Treasury, determines that there is a computer model investment advice program that may be utilized by an IRA to provide investment advice to the account beneficiary which meets the requirements described in PPA section 601(b)(3)(B).[5]

On December 4, 2006, the Department published two Requests for Information in the **Federal Register** soliciting information to assist the Department in the development of regulations under ERISA section 408(b)(14) and 408(g), and in making its determination with respect to the utilization of computer models for IRAs. 71 FR 70429; 71 FR 70427. Concurrent with the publication of this document, the Department reported to Congress its determination that there exist computer models that meet the requirements described in PPA section 601(b)(3)(B). In addition, appearing elsewhere in today's **Federal Register**, the Department is publishing proposed regulations that would implement the provisions of the statutory exemption for the provision of investment advice to participants and beneficiaries under sections 408(b)(14) and 408(g), and parallel provisions in Code section 4975.

This class exemption is intended to complement the adoption of those implementing regulations by furthering the availability of individualized investment advice to both participants and beneficiaries in participant-directed individual account plans and IRA beneficiaries under circumstances not encompassed in the statutory exemption or implementing regulations, as described below.

notice to specific sections of ERISA should be taken as referring also to the corresponding sections of the Code.

[5] PPA section 601(b)(3)(C)(i).

B. Overview of Proposed Class Exemption

1. General

In general, the proposed class exemption, like the statutory exemption and proposed regulations published thereunder (proposed 29 CFR 2550.408g–1), provides relief from otherwise prohibited transactions relating to the provision of investment advice to the participant or beneficiary with respect to a security or other property available as an investment under a plan or IRA; the acquisition, holding or sale of a security or other property available as an investment under a plan or IRA pursuant to the investment advice; and the direct or indirect receipt of compensation by a fiduciary adviser or affiliate in connection with the provision of investment advice or the acquisition, holding or sale of a security or other property available as an investment under the plan or IRA pursuant to the investment advice.

Unlike the statutory exemption and proposed regulations, however, the class exemption would provide relief for individualized investment advice to individuals following the furnishing of recommendations generated by a computer model or, in the case of IRAs with respect to which modeling is not feasible, the furnishing of certain investment education material. The computer generated advice recommendations and investment education materials are intended to provide individual account plan participants and beneficiaries and IRA beneficiaries with a context for assessing and evaluating the individualized investment advice contemplated by the exemption. Also unlike the statutory exemption and proposed regulations, the class exemption, as discussed below, applies the fee-leveling limits solely to the compensation received by the employee, agent or registered representative providing the advice on behalf of the fiduciary adviser, as distinguished from compensation received by the fiduciary adviser on whose behalf the employee, agent or registered representative is providing such advice.

2. Scope of Exemption—Sections I and II

Sections I and II of the proposal define the scope of the class exemption. Section I provides that, with respect to the provision of advice to participants and beneficiaries of individual account plans, the restrictions of sections 406(a) and 406(b) of ERISA and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code, shall not apply to the provision of investment advice described in section 3(21)(A)(ii) of the Act by a fiduciary adviser to a participant or beneficiary of an individual account plan that permits such participant or beneficiary to direct the investment of their individual accounts; the acquisition, holding, or sale of a security or other property pursuant to the investment advice; and, except as otherwise provided in the exemption, the direct or indirect receipt of fees or other compensation by the fiduciary adviser (or any employee, agent, registered representative or affiliate thereof) in connection with the provision of the advice or in connection with an acquisition, holding, or sale of a security or other property pursuant to the investment advice. Section II provides the same relief with respect to the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code, for investment advice to beneficiaries of IRAs.

3. Conditions—Section III

General—Paragraphs (a)–(d)

Paragraphs (a) through (c) set forth general requirements relating to the arrangements and investment advice covered by the exemption, without regard to whether a fiduciary adviser uses a computer model or levels fees in connection with the providing of individualized investment advice. Paragraph (a) provides that the investment advice arrangement must be authorized by a plan fiduciary (or, in the case of an IRA, the IRA beneficiary) other than: the person offering the investment advice arrangement; any person providing designated investment options under the plan; or any affiliate of either. The terms designated investment options and affiliate are defined in Section IV, described below. Paragraph (a) further provides that for purposes of such authorization, an IRA beneficiary will not be treated as an affiliate of a person solely by reason of being an employee of such person, thereby, enabling employees of a fiduciary adviser to take advantage of the investment advice arrangements offered by their employer under the exemption. Paragraph (b) requires that the provided investment advice be based on certain generally accepted investment theories. Paragraph (c) requires that the investment advice must take into account information furnished by a participant or beneficiary.

Paragraph (d) of Section III requires that the fiduciary adviser must provide advice in accordance with paragraph (e) or paragraph (f) or both. As discussed below, paragraph (e) generally requires the provision of investment advice generated by a computer model in advance of providing individualized, non-computer modeled advice. Paragraph (f) requires that investment advice be provided in a manner with respect to which fees or other compensation received by an employee, agent or registered representative providing investment advice on behalf of a fiduciary adviser do not vary based on the investment option selected by the participant or beneficiary. Paragraph (d) also permit the provision of investment advice using a combination of computer generated advice and fee-leveling.

Use of Computer Models—Paragraph (e)

Paragraph (e)(1) requires that, prior to the provision of other investment advice covered by the class exemption, participants and beneficiaries must be furnished with investment recommendations generated by a computer model. The computer model must either meet the requirements of ERISA section 408(g)(3)(B) and (C) [6] or meet the requirements of section 408(g)(3)(B) and be designed and maintained by a person independent of the fiduciary adviser (and any of the adviser's affiliates) and utilize methodologies and parameters determined appropriate solely by the independent person. If the conditions of section III are satisfied, then the class exemption provides relief, as described in sections I and II, in connection with both the investment advice generated by the computer model and the non-computer model generated investment advice subsequently provided.

In order to satisfy paragraph (e)(1), a computer model must, at least, meet the requirements of section 408(g)(3)(B) and the regulations issued thereunder applicable to a computer model that serves as the basis of an eligible investment advice arrangement under the statutory exemption and related regulations (proposed 29 CFR 2550.408g–1(d)(1)). Additionally, unless the computer model is developed and maintained by a person independent of the fiduciary adviser (and its affiliates), the computer model must be certified, in accordance with ERISA section 408(g)(3)(C) and related regulations (proposed 29 CFR 2550.408g–1(d)(2)), as satisfying those requirements. Thus, unless the computer model is developed and maintained by an independent person, the model must meet the same requirements, including certification, as under the statutory exemption and related regulations. With respect to the inclusion of independently developed and maintained computer models under paragraph (e)(1), the Department opined in Advisory Opinion 2001–09A (Dec. 14, 2001) (AO 2001–09A) that an investment adviser providing investment advice regarding investments that pay additional fees to the adviser could avoid prohibited transaction issues under ERISA section 406(b)(1) and (3) by utilizing computer methodologies developed, maintained and overseen by an independent person to generate the advice provided. This continues to be the view of the Department.[7] However, as with investment advice provided under the statutory exemption, the Department believes that plan participants and beneficiaries may want the flexibility to obtain other investment advice after receiving computer-generated advice, and advisers may be willing to offer such services. Accordingly, paragraph (e)(1) similarly encompasses transactions in connection with investment advice received after investment advice generated by a computer model developed and maintained by a person independent of the fiduciary adviser and its affiliates. For purposes of this paragraph, the term ''independent'' is defined in paragraph (h) of Section IV. The Department notes, however, that it continues to believe that what constitutes ''independent'' for purposes of the analysis in AO 2001–09A is an inherently factual question,[8] and that no inferences should be drawn with regard to the effect of the definition contained in paragraph (h) of section IV on the analysis in AO 2001–09A.

The general requirement for computer model investment advice set forth in paragraph (e)(1) also applies to IRAs, unless the fiduciary adviser determines that the types or number of investment choices available to an IRA beneficiary reasonably precludes the use of a computer model meeting of the requirements of section ERISA 408(g)(3)(B). See paragraph (e)(2) of Section III. If the fiduciary adviser so concludes, paragraph (e)(2) of Section III requires that the beneficiary be provided certain investment education-type materials, such as graphs, pie charts, case studies, worksheets, or interactive software or similar programs, that reflect or produce asset allocation models taking into account the age (or time horizon) and risk profile of the beneficiary, to the extent known. Paragraph (e)(2) also sets forth some general standards intended to ensure the reasonableness and objectivity of the materials furnished. These materials, like the investment advice generated by a computer model required under paragraph (e)(1), are intended to provide a means by which a participant or beneficiary may assess the individualized advice provided by the fiduciary adviser, taking into account whether and to what extent the individualized advice deviates from the computer generated advice or education-type materials furnished in advance by the fiduciary adviser.

Paragraph (e)(3) of Section III requires that the investment advice provided does not recommend investment options that may generate for the fiduciary adviser, or certain other persons, greater income than other options of the same asset class, unless the fiduciary adviser prudently concludes that the recommendation is in the best interest of the participant or beneficiary and explains the basis for that conclusion to the participant or beneficiary. Section III(e)(4), described below, imposes a specific documentation requirement with respect to any such advice. Section III(e)(3) does not apply to investment advice generated solely by use of a computer model described in paragraph (e)(1)(A) or (B) of section III.

Paragraph (e)(4) of Section III generally requires that not later than 30 days following the provision of investment advice under paragraph (e), the individual providing the advice on behalf of the fiduciary adviser must document the basis of any investment option(s) recommended to a participant or beneficiary, including an explanation

[6] In general, paragraph (3)(B) of section 408(g) provides that a computer model under an investment advice program must apply certain generally accepted investment theories, utilize relevant information about the participant, utilize prescribed objective criteria to provide asset allocation portfolios comprised of investment options available under the plan, operate in a manner that is not biased in favor of certain investments, and take into account all investment options under the plan in specifying how a participant's account balance should be invested. Paragraph (3)(C) of section 408(g) requires that a computer model utilized under an investment advice program be certified as meeting the requirements of paragraph (3)(B) by an eligible investment expert. Proposed regulations being published in today's **Federal Register** provide further guidance with respect to the computer model requirements contained in ERISA section 408(g)(3).

[7] *See* Field Assistance Bulletin 2007–01 (February 2, 2007).

[8] *See* AO 2001–09A, footnote 11 (''whether a party is 'independent' for purposes of the subject analysis will generally involve a determination as to whether there exists a financial interest (*e.g.*, compensation, fees, etc.), ownership interest, or other relationship, agreement or understanding that would limit the ability of the party to carry out its responsibility beyond the control, direction or influence of the fiduciary'').

as to how such recommendation relates to the recommendations or information provided or generated pursuant to paragraph (e)(1) or, if applicable, paragraph (e)(2). As an example, in the case of an IRA described in paragraph (e)(2) with respect to which a fiduciary adviser provides several generic asset allocation portfolios prior to rendering investment advice, the documentation required by paragraph (e)(4) must include explanations as to the asset allocation portfolio on which the investment advice is based, including reasons for its selection or deviation from those provided, and how the recommended investments provide the appropriate asset class exposures consistent with the portfolio.

Paragraph (e)(4) further requires that with respect to any investment advice that recommends investment options that may generate for the fiduciary adviser, or certain persons, greater income than other options of the same asset class, the individual providing the investment advice on behalf of the fiduciary adviser must, not later than 30 days following its provision, document the basis for concluding that the recommendation is in the best interest of the participant or beneficiary. As with the requirements of paragraph (e)(3), this requirement does not apply to investment advice generated solely by use of a computer model described in paragraph (e)(1)(A) or (B) of Section III.

Paragraph (e)(5) provides that the documentation required by paragraph (e)(4) must be retained in accordance with the exemption's record-retention provision, section paragraph (n) of Section III, described below.

Use of Fee-Leveling—Paragraph (f)

Paragraph (f) of Section III requires that any fees or other compensation (including salary, bonuses, awards, promotions, commissions or any other thing of value) received, directly or indirectly, by an employee, agent or registered representative providing advice on behalf of the fiduciary adviser pursuant to the class exemption do not vary depending on the basis of any investment option selected by a participant or beneficiary. The Department notes that, in contrast to the fee-leveling requirement under the statutory exemption as described above and interpreted in proposed regulations being published in today's **Federal Register**, the fee-leveling requirement under paragraph (f) applies *only* to the individual who provides investment advice. In this regard, the Department is persuaded that the safeguards provided for in the class exemption are sufficient to permit the application of the fee-leveling requirement at the individual-level, rather than fiduciary adviser-entity level, without compromising the availability of informed, unbiased, and objective investment advice for participants and beneficiaries.

Disclosure—Paragraphs (g)–(h)

The disclosure provisions set forth in paragraph (g) of Section III generally track the disclosure provisions of the proposed regulations. See proposed 29 CFR 2550.408g–1(g). In this regard, paragraph (g) of Section III requires that a fiduciary adviser furnish certain information, without charge, to a participant or beneficiary in advance of the initial provision of investment advice under the class exemption, and at least once each year thereafter during which the adviser provides investment advice to the participant or beneficiary under the class exemption.

Pursuant to paragraph (g)(1), a fiduciary adviser is required to provide to participants and beneficiaries a written notification describing: The role of any party that has a material affiliation or material contractual relationship with the fiduciary adviser in the development of the computer model described in paragraph (e)(1) or materials described in section paragraph (e)(2) of Section III and in the selection of investment options available under the plan; the past performance and historical rates of return of the designated investment options available under the plan or IRA to the extent such information is not otherwise provided; all fees or other compensation relating to the advice that the fiduciary adviser or any affiliate thereof is to receive (including compensation provided by any third party) in connection with the provision of the advice or in connection with the sale, acquisition, or holding of the security or other property; and of any material affiliation or material contractual relationship of the fiduciary adviser or affiliates thereof in the security or other property.

The notification also is required to explain the manner, and under what circumstances, any participant or beneficiary information provided under the investment advice arrangement will be used or disclosed, and the types of services provided by the fiduciary adviser in connection with the provision of investment advice by the fiduciary adviser, including, with respect to an arrangement that utilizes a computer model pursuant to paragraph (e)(1), any limitations on the ability of the computer model to take into account an investment option that constitutes an investment primarily in qualifying employer securities, as provided for in proposed 29 CFR 2550.408g–1(d)(1)(v). This disclosure of limitations on a computer model's ability to take into account investments in qualifying employer securities parallels a similar requirement contained in the proposed regulations under section 408(g)(3) being published today.[9]

In addition to the foregoing, the notification must inform participants and beneficiaries that the fiduciary adviser is acting as a fiduciary of the plan in connection with the provision of the advice, and that the participants or beneficiaries may separately arrange for the provision of advice by another adviser, that could have no material affiliation with, and receives no fees or other compensation in connection with, the security or other property recommended to the participant or beneficiary.

Paragraph (g)(2)(i) provides that the information furnished pursuant to paragraph (g)(1) must be written in a clear and concise manner and in a manner calculated to be understood by the average plan participant and is sufficiently accurate and comprehensive to reasonably apprise such participants and beneficiaries of the information required to be disclosed. Paragraph (g)(2)(ii) notes that the appendix to proposed 29 CFR 2550.408g–1 contains a model disclosure form that may be used to provide the required notification of information described in paragraph (g)(1)(iii). Paragraph (g)(2)(ii) makes clear that use of the model is voluntary. However, use of an appropriately completed model disclosure form will be deemed to satisfy the requirements of paragraphs (g)(1) and (2)(i) with respect to such information.

Paragraph (g)(3) indicates that required notification may be provided in written or electronic form.

Paragraph (g)(4) requires that the fiduciary adviser provide, without charge, updated information to the advice recipient concerning any material change to the information required to be provided to the advice recipient under section III(g) at a time reasonably contemporaneous to the change in information.

Paragraph (h) requires that the fiduciary adviser provide appropriate disclosure, in connection with the sale, acquisition, or holding of the security or other property, in accordance with all applicable securities laws.

[9] For a description of computer model limitations, see proposed regulations published in today's **Federal Register**.

Policies and Procedures—Paragraph (i)

Paragraph (j) of Section III requires that the fiduciary adviser adopt and follow written policies and procedures that are designed to assure compliance with the conditions of the exemption. The Department believes that the maintenance of such policies and procedures will help ensure compliance with the exemption, as well as support a finding that, for purposes of section 408(a)(1), the exemption is administratively feasible. In this regard, the Department notes that, as discussed below, the auditor engaged pursuant to paragraph (j) is required to review a fiduciary adviser's compliance with its policies and procedures.

Annual Audit—Paragraph (j)

The annual audit requirements of this proposed class exemption generally track the audit requirements applicable to investment advice arrangements offered under the statutory exemption and regulations issued thereunder, appearing elsewhere in today's **Federal Register**. See proposed 29 CFR 2550.408g–1(f).

Paragraph (j)(1)(i) of Section III of the proposed class exemption requires that, at least annually, the fiduciary adviser engage an independent auditor to conduct an audit, and prepare a report with respect thereto and setting forth its specific findings, to determine compliance with the policies and procedures required under paragraph (i) of Section III and the requirements of the class exemption. The auditor, within 60 days following the completion of the audit, must furnish its report to the fiduciary adviser and, except with respect to an arrangement with an IRA, to the fiduciary that authorized the investment advice arrangement, as required under paragraph (a) of Section III. The audit must be conducted by an auditor who has appropriate technical training or experience and proficiency and so represents in writing to the fiduciary adviser. Paragraph (j)(2) provides that for purposes of paragraph (j)(1), an auditor is considered independent if it does not have a material affiliation or material contractual relationship with the person offering the investment advice arrangement to the plan or IRA or any person providing designated investment options under the plan or IRA.

Paragraph (j)(1)(ii) contains additional requirements that apply with respect to an arrangement with an IRA. Under this provision, the fiduciary adviser, within 30 days following receipt of the report from the auditor, as described in paragraph (j)(1)(i), must furnish a copy of the report to the IRA beneficiary or make such report available on its *Web site,* provided, however, that with respect to availability on a *Web site,* such IRA beneficiaries must be provided information, with the information required to be furnished pursuant to section III(g)(1), concerning the purpose of the report, and how and where to locate the report applicable to their account. With respect to making the report available on a *Web site,* the Department believes that this alternative to furnishing reports to IRA beneficiaries satisfies the requirement of section 104(d)(1) of the Electronic Signatures in Global and National Commerce Act (E–SIGN) [10] that any exemption from the consumer consent requirements of section 101(c) of E–SIGN must be necessary to eliminate a substantial burden on electronic commerce and will not increase the material risk of harm to consumers. The Department solicits comments on this finding. Further, in the event that the report of the auditor identifies noncompliance with the policies and procedures required by section III(i) or the conditions of the class exemption, the fiduciary adviser, within 30 days following receipt of the report from the auditor, must send a copy of the report to the Department at the address provided in the class exemption.

Paragraph (j)(3) provides that, in conducting the audit required in (j)(1), the auditor must review sufficient relevant information to formulate an opinion as to whether the investment advice arrangements, and the advice provided pursuant thereto, offered by the fiduciary adviser during the audit period were in compliance with the policies and procedures required under paragraph (i) of Section III and the requirements of the class exemption. Paragraph (j)(3) also makes clear, however, that it does not preclude an auditor from using information obtained by sampling, as reasonably determined appropriate by the auditor, investment advice arrangements, and the advice pursuant thereto, during the audit period.

Miscellaneous Conditions—Paragraphs (k)–(m)

Paragraphs (k)–(m) track provisions of the statutory exemption and proposed regulations, appearing elsewhere in today's **Federal Register**. See proposed 29 CFR 2550.408g–1(h). Paragraph (k) of Section III requires that the sale, acquisition or holding of a security or other property on behalf of a plan or IRA under the exemption must occur solely at the direction of the recipient of the investment advice. Paragraph (l) requires that the compensation received by the fiduciary adviser and affiliates thereof in connection with the sale, acquisition or holding of the security or other property must be reasonable. Paragraph (m) requires that the terms of the sale, acquisition or holding of the security or other property must be at least as favorable to the plan or IRA as an arm's length transaction with an unrelated party would be.

Record Retention—Paragraph (n)

Paragraph (n) of Section III provides that the fiduciary adviser must maintain, in a manner accessible for audit or examination, for a period not less than six years after the provision of investment advice any records necessary to determine, explain or verify compliance with the conditions of the class exemption.

4. Definitions—Section IV

Section IV defines certain terms that apply for purposes of the class exemption. In general, the definitions applied for purposes of the class exemption comport with the definitions applied to terms under the statutory exemption and the proposed regulations, appearing elsewhere in today's **Federal Register**. See proposed 29 CFR 2550.408g–1(j).

As a threshold matter, this proposed class exemption would be available only in connection with investment advice provided by a fiduciary adviser. Paragraph (a) defines the term ''fiduciary adviser.'' This definition tracks the statutory definition of that term.

Paragraph (b) defines the term ''registered representative'' of another entity to mean a person described in section 3(a)(18) of the Securities Exchange Act of 1934 (substituting the entity for the broker or dealer referred to in such section) or a person described in section 202(a)(17) of the Investment Advisers Act of 1940 (substituting the entity for the investment adviser referred to in such section). Paragraph (c) defines the term ''individual retirement account'' and paragraph (d) defines the term ''affiliate'' for purposes of the class exemption.

As with the proposed regulations, the proposed class exemption, at paragraphs (e) and (f), respectively, also defines the terms ''material affiliation'' and ''material contractual relationship.'' Paragraph (e)(1) defines a person with a ''material affiliation'' with another person as: any affiliate of the other person; any person directly or indirectly owning, controlling, or holding, 5

[10] 15 U.S.C. 7004(d)(1) (2000).

percent or more of the interests of such other person; and any person 5 percent or more of whose interests are directly or indirectly owned, controlled, or held, by such other person. The Department notes that the definition of material affiliation includes an affiliate, as defined in paragraph (d) of section IV, and that, whereas the definition of affiliate focuses on voting securities owned, controlled or held, the definition of material affiliate focuses not only on the voting interests, but also on any interest. In this regard, paragraph (e)(2) defines the term ''interest'' for purposes of paragraph (e)(1).

Paragraph (f) provides that persons have a ''material contractual relationship'' if payments made by one person to the other person pursuant to written contracts or agreements between the persons exceed 10 percent of the gross revenue, on an annual basis, of such other person. The Department believes that one person's receipt of more than 10 percent of gross revenue from another person is sufficiently significant to be considered material. However, the Department specifically invites comments on whether the percentage test should be higher or lower and, if so, why.

Paragraph (g) defines ''control'' to mean the power to exercise a controlling influence over the management or policies of a person other than an individual.

Paragraph (h) of Section IV defines, for purposes of paragraph (e)(1) of Section III, the term ''independent'' to mean a person that is not an affiliate of the other person and does not have a material affiliation or material contractual relationship with the other person.

For purposes of paragraphs (a), (g)(1) and (j)(2) of Section III of the proposal, paragraph (i) of Section IV defines the term ''designated investment option'' to mean any investment option designated by the plan into which participants and beneficiaries may direct the investment of assets held in, or contributed to, their individual accounts. However, the term ''designated investment option'' does not include ''brokerage windows,'' ''self-directed brokerage accounts,'' or similar plan arrangements that enable participants and beneficiaries to select investments beyond those designated by the plan.

5. Effect of Noncompliance—Section V

Section V clarifies that the class exemption will not apply to any transaction (described in section I or II) in connection with the provision of investment advice to an individual participant or beneficiary with respect to which the conditions of the exemption have not been satisfied. In addition, in the case of a pattern or practice of noncompliance with any of the conditions, the exemption will not apply to any transaction in connection with the provision of investment advice provided by the fiduciary adviser during the period over which the pattern or practice extended.

C. Effective Date

The Department is proposing an effective date for the proposed class exemption which is 90 days after the publication of the final exemption in the **Federal Register**.

D. General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act. Section 404 requires, among other things, that a fiduciary discharge its duties with respect to the plan prudently and solely in the interests of the plan's participants and beneficiaries. A transaction's qualification for an exemption also does not affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) If granted, the proposed exemption will apply to a transaction only if the conditions specified in the exemption are met; and

(3) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules.

E. Written Comments

Interested persons are encouraged to submit written comments on the proposed exemption. Comments are due not later than 45 days after the date of publication of the proposal in the **Federal Register**. The Employee Benefits Security Administration encourages interested persons to submit their comments electronically by e-mail to *e-ORI@dol.gov* (Subject: Investment Advice Class Exemption). Persons submitting comments electronically are encouraged not to submit paper copies. Persons interested in submitting paper copies should refer to the information set forth above under **ADDRESSES** for the specific information relating to the delivery comments. All comments will be available to the public, without charge, online at *http://www.dol.gov/ebsa* and at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

F. Executive Order 12866; Paperwork Reduction Act

The Department's full Regulatory Impact Analysis for the class exemption proposed herein and rules proposed under the statutory exemption for investment advice can be found in the preamble to those proposed rules appearing elsewhere in today's **Federal Register** .

G. Proposed Exemption

The Department has under consideration the grant of the following class exemption under the authority of section 408(a) of ERISA and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).

Section I—Proposed Exemption for the Provision of Investment Advice to Participants and Beneficiaries of Individual Account Plans

The restrictions of sections 406(a) and 406(b) of ERISA and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code, shall not apply to:

(a) The provision of investment advice described in section 3(21)(A)(ii) of the Act by a fiduciary adviser to a participant or beneficiary of an individual account plan that permits such participant or beneficiary to direct the investment of their individual accounts;

(b) the acquisition, holding, or sale of a security or other property pursuant to the investment advice; and

(c) except as otherwise provided in this exemption, the direct or indirect receipt of fees or other compensation by the fiduciary adviser (or any employee, agent, registered representative or affiliate thereof) in connection with the provision of the advice or in connection with an acquisition, holding, or sale of a security or other property pursuant to the investment advice, provided that the conditions set forth in section III below are met.

Section II—Proposed Exemption for the Provision of Investment Advice to Beneficiaries of Individual Retirement Accounts

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code, shall not apply to:

(a) The provision of investment advice described in section 4975(e)(3)(B) of the Code by a fiduciary adviser to a beneficiary of an Individual Retirement Account (IRA) that permits such beneficiary to direct the investment of the assets of his or her IRA;

(b) the acquisition, holding, or sale of a security or other property pursuant to the investment advice; and

(c) except as otherwise provided in this exemption, the direct or indirect receipt of fees or other compensation by the fiduciary adviser (or any employee, agent, registered representative or affiliate thereof) in connection with the provision of the advice or in connection with an acquisition, holding, or sale of a security or other property pursuant to the investment advice, provided that the conditions set forth in section III below are met.

Section III. Conditions

(a) The arrangement pursuant to which investment advice is provided to participants and beneficiaries is expressly authorized in advance by a plan fiduciary (or, in the case of an IRA, the IRA beneficiary) other than: The person offering the investment advice arrangement; any person providing designated investment options under the plan; or any affiliate of either. Provided, however, that for purposes of the preceding, in the case of an IRA, an IRA beneficiary will not be treated as an affiliate of a person solely by reason of being an employee of such person.

(b) The investment advice is based on generally accepted investment theories that take into account the historic returns of different asset classes over defined periods of time; provided, however, that nothing herein shall preclude any investment advice from being based on generally accepted investment theories that take into account additional considerations.

(c) The investment advice takes into account information furnished by a participant or beneficiary relating to age, life expectancy, retirement age, risk tolerance, other assets or sources of income and investment preferences, although nothing herein shall preclude any investment advice from taking into account additional information that a participant or beneficiary may provide.

(d) The fiduciary adviser provides advice in accordance with paragraph (e) or (f), or both.

(e)(1) Except as provided in subparagraph (2), before providing other investment advice covered by this exemption, participants and beneficiaries shall be furnished with investment recommendations generated by a computer model that—(A) meets the requirements of ERISA section 408(g)(3)(B) and (C); or (B) meets the requirements of section 408(g)(3)(B) and was designed and is maintained by a person independent of the fiduciary adviser (and any of the adviser's affiliates) and utilizes methodologies and parameters determined appropriate solely by the independent person, without influence from the fiduciary adviser (or any of the adviser's affiliates);

(2) In the case of an IRA with respect to which the types or number of investment choices reasonably precludes the use of a computer model meeting the requirements of section 408(g)(3)(B) of ERISA to generate investment recommendations, before providing other investment advice covered by this exemption, beneficiaries shall be furnished with material, such as graphs, pie charts, case studies, worksheets, or interactive software or similar programs, that reflect or produce asset allocation models taking into account the age (or time horizon) and risk profile of the beneficiary, to the extent known. Nothing shall preclude the furnishing of material, in addition to the foregoing, reflecting asset allocation portfolios of hypothetical individuals with different time horizons and risk profiles. For purposes of any materials provided pursuant to this subparagraph (2): (A) models must be based on generally accepted investment theories that take into account the historic returns of different asset classes (*e.g.*, equities, bonds, or cash) over defined periods of time; (B) such models must operate in a manner that is not biased in favor of investments offered by the fiduciary adviser or a person with a material affiliation or material contractual relationship with the fiduciary adviser; and (C) all material facts and assumptions on which such models are based (*e.g.*, retirement ages, life expectancies, income levels, financial resources, replacement income ratios, inflation rates, and rates of return) accompany the models;

(3) The investment advice provided does not recommend investment options that may generate for the fiduciary adviser or any employee, agent or registered representative, or any affiliate thereof, or any person with a material affiliation or material contractual relationship with the foregoing, greater income than other options of the same asset class, unless the adviser prudently concludes that the recommendation is in the best interest of the participant or beneficiary and explains the basis for that conclusion to the participant or beneficiary. This subparagraph (3) shall not apply to investment advice generated solely by use of a computer model described in clause (A) or (B) of subparagraph (1);

(4) Not later than 30 days following the provision of investment advice under this paragraph (e), the employee, agent or registered representative providing the advice on behalf of the fiduciary adviser shall document the basis of any investment option(s) recommended to a participant or beneficiary, including an explanation as to how such recommendation relates to the recommendations or information provided or generated pursuant to subparagraph (1) or (2) of this paragraph (e); and, with respect to any investment advice (other than generated solely by a computer model described in clause (A) or (B) of subparagraph (1)) that recommends investment options that may generate for the fiduciary adviser or any employee, agent or registered representative, or any affiliate thereof, or any person with a material affiliation or material contractual relationship with the foregoing, greater income than other options of the same asset class, the basis for concluding that the recommendation is in the best interest of the participant or beneficiary;

(5) Any documentation required by subparagraph (4) of this paragraph (e) shall be retained in accordance with paragraph (n) of this section.

(f) Any fees or other compensation (including salary, bonuses, awards, promotions, commissions or any other thing of value) received, directly or indirectly, by an employee, agent or registered representative providing advice on behalf of the fiduciary adviser pursuant to this exemption (as distinguished from any compensation received by the fiduciary adviser on whose behalf the employee, agent or registered representative is providing such advice) do not vary depending on the basis of any investment option selected by a participant or beneficiary.

(g)(1) The fiduciary adviser provides, without charge, to the participant or beneficiary before the initial provision of investment advice under this exemption, and at least once each year thereafter during which the fiduciary adviser provides investment advice to the participant or beneficiary, written notification: (i) Of the role of any party

that has a material affiliation or material contractual relationship with the fiduciary adviser in the development of the computer model described in paragraph (e)(1) of this section or, if applicable, the materials described in paragraph (e)(2) of this section, and, to the extent applicable, in the selection of investment options available under the plan, (ii) of the past performance and historical rates of return of the designated investment options available under the plan or IRA to the extent such information is not otherwise provided, (iii) of all fees or other compensation relating to the advice that the fiduciary adviser or any affiliate thereof is to receive (including compensation provided by any third party) in connection with the provision of the advice or in connection with the sale, acquisition, or holding of the security or other property, (iv) of any material affiliation or material contractual relationship of the fiduciary adviser or affiliates thereof in the security or other property, (v) of the manner, and under what circumstances, any participant or beneficiary information provided under the arrangement will be used or disclosed, (vi) of the types of services provided by the fiduciary adviser in connection with the provision of investment advice by the fiduciary adviser, including, with respect to an arrangement that utilizes a computer model pursuant to paragraph (e)(1), any limitations on the ability of the computer model to take into account an investment option that constitutes an investment primarily in qualifying employer securities, as provided for at 29 CFR 2550.408g–1(d)(1)(v), (vii) that the fiduciary adviser is acting as a fiduciary of the plan in connection with the provision of the investment advice, and (viii) that a recipient of the advice may separately arrange for the provision of advice by another adviser, that could have no material affiliation with, and receives no fees or other compensation in connection with, the security or other property;

(2)(i) Such notification must be written in a clear and conspicuous manner and in a manner calculated to be understood by the average plan participant and shall be sufficiently accurate and comprehensive to reasonably apprise such participants and beneficiaries of the information required to be disclosed; (ii) the appendix to 29 CFR 2550.408g–1 contains a model disclosure form that may be used to provide the notification of information described in paragraph (g)(1)(iii). Use of the model disclosure form is not mandatory. However, use of an appropriately completed model disclosure form will be deemed to satisfy the requirements of paragraphs (g)(1) and (2)(i) with respect to such information.

(3) Such notification may, in accordance with 29 CFR 2520.104b–1, be provided in written or electronic form.

(4) At all times during the provision of advisory services to the participant or beneficiary pursuant to this exemption, the fiduciary adviser provides, without charge, accurate information to the recipient of the advice concerning any material change to the information required to be provided to the recipient of the advice at a time reasonably contemporaneous to the change in information.

(h) The fiduciary adviser provides appropriate disclosure, in connection with the sale, acquisition, or holding of the security or other property, in accordance with all applicable securities laws.

(i) The fiduciary adviser adopts and follows written policies and procedures that are designed to assure compliance with the conditions of this exemption.

(j)(1) The fiduciary adviser—

(i) at least annually, engages an independent auditor, who has appropriate technical training or experience and proficiency and so represents in writing to the fiduciary adviser, to (A) conduct an audit, and prepare a report with respect thereto and setting forth its specific findings, to determine compliance with the policies and procedures of paragraph (i) of this section and the requirements of this exemption, and (B) within 60 days following the completion of the audit, furnish its report to the fiduciary adviser, and, except with respect to an arrangement with an IRA, to the fiduciary who authorized the arrangement pursuant to which investment advice under this exemption is provided; and

(ii) with respect to an arrangement with an IRA—(A) within 30 days following receipt of the report from the auditor, furnishes a copy of the report to the IRA beneficiary or makes such report available on its *Web site,* provided that such beneficiaries are provided information, with the information required to be disclosed pursuant to paragraph (g)(1) of this section, concerning the purpose of the report, and how and where to locate the report applicable to their account, and (B) in the event that the report of the auditor identifies noncompliance with the policies and procedures required by paragraph (i) or the conditions of this exemption, within 30 days following receipt of the report from the auditor, sends a copy of the report to the Department of Labor at the following address: Investment Advice Class Exemption Notification, U.S. Department of Labor, Employee Benefits Security Administration, Room N–1513, 200 Constitution Ave., NW., Washington, DC 20210;

(2) for purposes of subparagraph (1), an auditor is considered independent if it does not have a material affiliation or material contractual relationship with the person offering the investment advice arrangement to the plan or IRA or any designated investment options under the plan or IRA;

(3) for purposes of the audit described in subparagraph (1), the auditor shall review sufficient relevant information to formulate an opinion as to whether the investment advice arrangements, and the advice provided pursuant thereto, offered by the fiduciary adviser during the audit period were in compliance with the policies and procedures of paragraph (i) of this section and the requirements of this exemption; provided, however, that nothing in this subparagraph shall preclude an auditor from using information obtained by sampling, as reasonably determined appropriate by the auditor, investment advice arrangements, and the advice pursuant thereto, during the audit period.

(k) The sale, acquisition or holding of a security or other property on behalf of a plan or IRA occurs solely at the direction of the recipient of the investment advice.

(l) The compensation received by the fiduciary adviser and affiliates thereof in connection with the sale, acquisition or holding of the security or other property is reasonable.

(m) The terms of the sale, acquisition or holding of the security or other property are at least as favorable to the plan or IRA as an arm's length transaction would be.

(n) The fiduciary adviser maintains, in a manner accessible for audit or examination, for a period not less than six years after the provision of investment advice under this exemption, any records necessary to determine, explain or verify compliance with the conditions of this exemption.

Section IV. Definitions

(a) Fiduciary Adviser—means, with respect to a plan, a person who is a fiduciary of the plan by reason of the provision of investment advice described in section 3(21)(A)(ii) of the Act by the person to the participant or beneficiary of the plan and who is—

(1) Registered as an investment adviser under the Investment Advisers Act of 1940 (15 U.S.C. 80b–1 *et seq.*) or under the laws of the State in which the fiduciary maintains its principal office and place of business,

(2) A bank or similar financial institution referred to in section 408(b)(4) of the Act or a savings association (as defined in section 3(b)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1813(b)(1)), but only if the advice is provided through a trust department of the bank or similar financial institution which is subject to periodic examination and review by Federal or State banking authorities, or

(3) An insurance company qualified to do business under the laws of a State, or

(4) A person registered as a broker or dealer under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), or

(5) An affiliate of a person described in any of clauses (1) through (4) above, or

(6) An employee, agent, or registered representative of a person described in clauses (1) through (5) above who satisfies the requirements of applicable insurance, banking, and securities laws relating to the provision of the advice.

(b) Registered Representative—a registered representative of another entity means a person described in section 3(a)(18) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(18)) (substituting the entity for the broker or dealer referred to in such section) or a person described in section 202(a)(17) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–2(a)(17)) (substituting the entity for the investment adviser referred to in such section).

(c) Individual Retirement Account or IRA means—(1) an individual retirement account described in section 408(a) of the Code; (2) an individual retirement annuity described in section 408(b) of the Code; (3) an Archer MSA described in section 220(d) of the Code; (4) a health savings account described in section 223(d) of the Code; (5) a Coverdell education savings account described in section 530 of the Code; or (6) a trust, plan, account, or annuity which, at any time, has been determined by the Secretary of the Treasury to be described in any preceding subparagraph of this paragraph [*i.e.,* (1) through (5) above].

(d) Affiliate—unless specifically provided otherwise, an affiliate of another person means—

(1) Any person directly or indirectly owning, controlling, or holding with power to vote, 5 percent or more of the outstanding voting securities of such other person;

(2) Any person 5 percent or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such other person;

(3) Any person directly or indirectly controlling, controlled by, or under common control with, such other person; and

(4) Any officer, director, partner, copartner, or employee of such other person.

(e) Material Affiliation—(1) a person with a ''material affiliation'' with another person means—

(A) any affiliate of the other person;

(B) Any person directly or indirectly owning, controlling, or holding, 5 percent or more of the interests of such other person;

(C) Any person 5 percent or more of whose interests are directly or indirectly owned, controlled, or held, by such other person.

(2) For purposes of subparagraph (e)(1) of this section, the term ''interest'' means with respect to an entity—

(A) The combined voting power of all classes of stock entitled to vote or the total value of the shares of all classes of stock of the entity if the entity is a corporation;

(B) The capital interest or the profits interest of the entity if the entity is a partnership; or

(C) The beneficial interest of the entity if the entity is a trust or unincorporated enterprise.

(f) Material Contractual Relationship—persons have a ''material contractual relationship'' if payments made by one person to the other person pursuant to written contracts or agreements between the persons exceed 10 percent of the gross revenue, on an annual basis, of such other person.

(g) Control—means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(h) Independent—for purposes of section III(e)(1), a person is ''independent'' of another person if it is not an affiliate of the other person, and does not have a material affiliation or material contractual relationship with the other person.

(i) Designated Investment Option—means any investment option designated by the plan into which participants and beneficiaries may direct the investment of assets held in, or contributed to, their individual accounts. The term ''designated investment option'' shall not include ''brokerage windows,'' ''self-directed brokerage accounts,'' or similar plan arrangements that enable participants and beneficiaries to select investments beyond those designated by the plan.

Section V. Noncompliance With Terms of the Exemption

This exemption shall not apply to any transaction (described in Section I or II of this exemption) in connection with the provision of investment advice to an individual participant or beneficiary with respect to which the conditions of this exemption have not been satisfied. In addition, in the case of a pattern or practice of noncompliance with any of the conditions of this exemption, the exemption shall not apply to any transaction in connection with the provision of investment advice provided by the fiduciary adviser during the period over which the pattern or practice extended.

Signed at Washington, DC, this 15th day of August, 2008.

Bradford P. Campbell,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

[FR Doc. E8–19273 Filed 8–21–08; 8:45 am]

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Eurocopter France Model AS355E, F, F1, F2, and N Helicopters; comments due by 8-29-08; published 6-30-08 [FR E8-14723]

Pilatus Aircraft Ltd. Model PC-6 Series Airplanes; comments due by 8-29-08; published 7-30-08 [FR E8-17331]

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Offer of Cash Deposits or Obligations of the United States; comments due by 8-25-08; published 7-11-08 [FR E8-14858]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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H.R. 4040/P.L. 110–314

Consumer Product Safety Improvement Act of 2008 (Aug. 14, 2008; 122 Stat. 3016)

H.R. 4137/P.L. 110–315

Higher Education Opportunity Act (Aug. 14, 2008; 122 Stat. 3078)

H.R. 6432/P.L. 110–316

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, to establish a program of fees relating to generic new animal drugs, to make certain technical corrections to the Food and Drug Administration Amendments Act of 2007, and for other purposes. (Aug. 14, 2008; 122 Stat. 3509)

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