government agencies; elected officials; environmental and public interest groups; affected landowners; other interested parties; Native American tribes; local newspapers and libraries; and the FERC's official service list for this proceeding. A 30-day comment period will be allotted for review of the EA. We will consider all comments on the EA in any Commission Order that is issued for the project.

We have held early discussions with other jurisdictional agencies to identify their issues and concerns. These agencies include the U.S. Army Corps of Engineers, Nashville District; Tennessee Wildlife Resources Agency; and the Tennessee Department of Environment and Conservation, Divisions of Natural Heritage and Water Pollution Control. With this notice, we are asking these and other federal, state, and local agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. Agencies that would like to request cooperating status should follow the instructions for filing comments provided below.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the proposal. Your comments should focus on the potential environmental effects, reasonable alternatives (including alternative locations/routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please mail your comments so that they will be received in Washington, DC on or before March 3, 2005, and carefully follow these instructions:

- Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426;
- Label one copy of your comments for the attention of Gas Branch 1; DG2E; and
- Reference Docket No. PF05–2–000 on the original and both copies.

The public scoping meeting to be held on February 24, 2005 in Gallatin, TN is designed to provide another opportunity to offer comments on the proposed project. Interested groups and individuals are encouraged to attend this meeting and to present comments on the environmental issues they believe should be addressed in the EA. Transcripts of the meeting will be made so that your comments will be accurately recorded.

Please note that the Commission encourages electronic filing of comments. *See* 18 Code of Federal Regulations 385.2001(a)(1)(iii) and the instructions on the Commission's Internet Web site at *http://www.ferc.gov* under the ''eFiling'' link and the link to the User's Guide. Prepare your submission in the same manner as you would if filing on paper and save it to a file on your hard drive. Before you can file comments you will need to create an account by clicking on ''Login to File'' and then ''New User Account''. You will be asked to select the type of filing you are making. This filing is considered a ''Comment on Filing''.

When MGT submits its application for authorization to construct and operate the MGT Eastern Extension Project, the Commission will publish a Notice of Application in the **Federal Register** and will establish a deadline for interested persons to intervene in the proceeding. Because the Commission's NEPA Pre-filing Process occurs before an application to begin a proceeding is officially filed, petitions to intervene during this process are premature and will not be accepted by the Commission.

Environmental Mailing List

An effort is being made to send this notice to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project. This includes all landowners who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within distances defined in the Commission's regulations of certain above-ground facilities. If you wish to remain on our environmental mailing list, please return the Information Request Form included in Appendix 2. If you do not return this form, you will be removed from our mailing list.

Availability of Additional Information

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is also available for viewing on the FERC Internet website. This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Additional information about the project is available from the Commission's Office of External Affairs at 1–866–208–FERC (3372) or on the FERC Internet Web site (*http://www.ferc.gov*). Using the ''eLibrary'' link, select General Search from the ''eLibrary'' menu, enter the selected date range and Docket Number (*i.e.*, PF05–2), and follow the instructions. Searches may also be done using the phrase MGT Extension Project in the Text Search field. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The ''eLibrary'' link on the FERC Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

In addition, the FERC now offers a free service called ''eSubscription'' that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. To register for this service, go to *http://www.ferc.gov/esubscribenow.htm.*

Finally, MGT has established an Internet Web site for its project at *http://www.mgt.nborder.com.* The Web site includes a description of the project, overview map, contact information for MGT, and links to related documents.

Magalie R. Salas,

Secretary.

[FR Doc. E5–337 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP04–36–000, CP04–41–000]

Weaver's Cove Energy, L.L.C., Mill River Pipeline, L.L.C.; Notice of Limited Additional Period for Comment

January 19, 2005.

On July 30, 2004, the Secretary of the Federal Energy Regulatory Commission (FERC or Commission) issued a Notice of Availability of the Draft Environmental Impact Statement (DEIS) and the Draft General Conformity Determination for the Proposed Weaver's Cove LNG Project, in the above-docketed proceedings. Comments on the draft EIS were due to the Secretary by September 20, 2004. As described below in this Notice, because it took the Commission time to process the requests described in the following paragraph, we will allow a limited opportunity for those who receive additional information to submit

supplemental comments based on that information. Responses will be included in the Final Environmental Impact Statement.

The Commission has received numerous requests under its critical energy infrastructure information (CEII) regulation, 18 CFR 388.113, for several documents filed as CEII by Weaver's Cover Energy, L.L.C. (Weaver's Cove). The Commission and the Commission's CEII Coordinator are currently processing these requests. To the extent that a CEII request existing as of January 19, 2005 is granted, notice is given that any such requester is hereby given a period of thirty calendar days after the additional information is made available to the requester within which to submit any additional comments on the DEIS related to the information obtained as part of the CEII request.

Magalie R. Salas,

Secretary.

[FR Doc. E5–342 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[P–2601–007]

Duke Power; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

January 21, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent minor license.

b. *Project No.:* 2601–007.

c. *Date filed:* July 22, 2003.

d. *Applicant:* Duke Power.

e. *Name of Project:* Bryson Hydroelectric Project.

f. *Location:* On the Oconaluftee River, in Swain County, North Carolina. The project does not affect Federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* John C. Wishon, Nantahala Area Relicensing Project Manager, Duke Power, 301 NP&L Loop, Franklin, NC 28734, (828) 369–4604, *jcwishon@duke-energy.com*.

i. *FERC Contact:* Carolyn Holsopple at (202) 502–6407 or *carolyn.holsopple@ferc.gov*.

j. Deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, 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.

Comments, recommendations, terms and conditions, 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 ''eLibrary'' link.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The existing Bryson Hydroelectric Project operates in a run-of-river mode, within a 6-inch tolerance band. Project operation is dependent on available flow in the Oconaluftee River. The project consists of the following features: (1) A 341-foot-long, 36-foot-high concrete multiple arch dam, consisting of, from left to right facing downstream, (a) a concrete, non-overflow section, (b) two gravity spillway sections, each surmounted by a 16.5-foot-wide by 16-foot-high Tainter gate, and (c) an uncontrolled multiple-arch spillway with four bays; (2) a 1.5-mile-long, 38-acre impoundment at elevation 1828.41 mean sea level (msl); (3) two intake bays, each consisting of an 8.5-foot-diameter steel intake pipe with a grated trashrack having a clear bar spacing of between 2.25 to 2.5 inches; (4) a powerhouse having a brick and concrete superstructure and concrete substructure, containing two turbine/generating units, having a total installed capacity of 980 kilowatts (kW); (5) a switchyard, with three single-phased transformers; and (6) appurtenant facilities.

Duke Power estimates that the average annual generation is 5,534,230 kilowatt hours (kWh). Duke Power uses the Bryson Project facilities to generate electricity for use by retail customers living in the Duke Power-Nantahala Area.

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.

You may also 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. Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

All filings must (1) bear in all capital letters the title ''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 submitting the filing; 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. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

Magalie R. Salas,

Secretary.

[FR Doc. E5–332 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[P–2602–007]

Duke Power; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

January 21, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Surrender of License.

b. *Project No.:* 2602–007.

c. *Date filed:* May 26, 2004.

d. *Applicant:* Duke Power.

e. *Name of Project:* Dillsboro Hydroelectric Project.

f. *Location:* On the Tuckasegee River, in Jackson County, North Carolina. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* John C. Wishon, Nantahala Area Relicensing Project Manager, Duke Power, 301 NP&L Loop, Franklin, NC 28734, (828) 369–4604, *jcwishon@duke-energy.com*

i. *FERC Contact:* Carolyn Holsopple at (202) 502–6407 or *carolyn.holsopple@ferc.gov.*

j. Deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, 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.

Comments, recommendations, terms and conditions, 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. Duke Power filed an application to surrender its major license for the Dillsboro Hydroelectric Project. Duke requests that the Commission approve the following: (1) Continue operating the Dillsboro Project under the terms of the current license until dam removal begins; (2) Decommission the dam and powerhouse and complete dam removal and powerhouse closure/removal within three years following the final FERC approval order; (3) Prepare and obtain FERC approval of, and implement an environmental monitoring plan in association with the dam removal, including completion of the Duke implemented portions of any post-removal stream restoration and annual monitoring within two years following completion of the dam removal. Also included in the surrender application was the Tuckasegee/Nantahala Settlement Agreements which were filed on January 26, 2004 as part of the relicense applications for the East Fork (P–2698), West Fork (P–2686), Nantahala (P–2692), Bryson (P–2601), Franklin (P–2603), and Mission (P–2619) Hydroelectric Projects. The settlement agreements provide various environmental enhancement measures, which include the removal of the Dillsboro Dam and Powerhouse.

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.

You may also 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. Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

All filings must (1) bear in all capital letters the title ''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 submitting the filing; 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. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

Magalie R. Salas,

Secretary.

[FR Doc. E5–333 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[P–2686–032]

Duke Power; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

January 21, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New major license.

b. *Project No.:* 2686–032.

c. *Date filed:* January 26, 2004.

d. *Applicant:* Duke Power.

e. *Name of Project:* West Fork Hydroelectric Project.

f. *Location:* On the West Fork of the Tuckasegee River, in Jackson County, North Carolina. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* John C. Wishon, Nantahala Area Relicensing Project Manager, Duke Power, 301 NP&L Loop, Franklin, NC 28734, (828) 369–4604, *jcwishon@duke-energy.com.*

i. *FERC Contact:* Carolyn Holsopple at (202) 502–6407 or *carolyn.holsopple@ferc.gov.*

j. Deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, 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.

Comments, recommendations, terms and conditions, 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 existing West Fork Project operates in a peaking mode and is comprised of two developments: Thorpe and Tuckasegee. The Thorpe development consists of the following features: (1) A 900-foot-long, 150-foot-tall rockfill dam (Glenville Dam), with a 410-foot-long, 122-foot-tall earth and rockfill saddle dam located approximately 500 feet from the main dam left abutment; (2) a spillway for Glenville Dam located at the right abutment; (3) a 1,462-acre reservoir, with a normal reservoir elevation of 3,491.8 feet National Geodetic Vertical Datum and a storage capacity of 72,000-acre-feet; (4) a concrete and brick powerhouse containing one generating unit having an installed capacity of 15.5 megawatts (MW); and (5) appurtenant facilities.

The Tuckasegee development consists of the following features: (1) A 254-foot-long, 61-foot-high concrete arch dam (Tuckasegee Dam), with 24 steel flashboards; (2) a 233.5-foot-long spillway; (3) a 7.9-acre reservoir, with a normal reservoir elevation of 2,778.75 feet National Geodetic Vertical Datum and a storage capacity of 35-acre-feet; (4) a concrete powerhouse containing one generating unit having an installed capacity of 2.6 MW; and (5) appurtenant facilities.

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.

You may also 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. Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

All filings must (1) bear in all capital letters the title ''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 submitting the filing; 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. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

Magalie R. Salas,

Secretary.

[FR Doc. E5–334 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[P–2692–032]

Duke Power; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

January 21, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2692–032.

c. *Date filed:* February 20, 2004.

d. *Applicant:* Duke Power.

e. *Name of Project:* Nantahala Hydroelectric Project.

f. *Location:* On the Nantahala River and its tributaries, in Macon and Clay Counties, North Carolina. There are 41 acres of United States Forest Service managed land (Nantahala National Forest) within the Nantahala Project boundary.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* John C. Wishon, Nantahala Area Relicensing Project Manager, Duke Power, 301 NP&L Loop, Franklin, NC 28734, (828) 369–4604, *jcwishon@duke-energy.com.*

i. *FERC Contact:* Carolyn Holsopple at (202) 502–6407 or *carolyn.holsopple@ferc.gov.*

j. Deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, 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.

Comments, recommendations, terms and conditions, 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 existing Nantahala Project operates in a peaking mode and consists of the following features: (1) A 1,042-foot-long, 250-foot-high earth and rockfill dam; (2) a spillway for the dam located at the east abutment; (3) a 1,605-acre reservoir, with a normal reservoir elevation of 3,012.2 feet National Geodetic Vertical Datum and a storage capacity of 38,336 acre-feet; (4) a reinforced concrete powerhouse containing one generating unit having an installed capacity of 42 megawatts (MW); (5) two stream diversions (Dicks Creek and Whiteoak Creek) that provide additional flow into the project; and (6) appurtenant facilities. 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.

You may also 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. Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

All filings must (1) Bear in all capital letters the title ''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 submitting the filing; 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. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

Magalie R. Salas,

Secretary.

[FR Doc. E5–335 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[P–2698–033]

Duke Power; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

January 21, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2698–033.

c. *Date filed:* February 20, 2004.

d. *Applicant:* Duke Power.

e. *Name of Project:* East Fork Hydroelectric Project.

f. *Location:* On the East Fork of the Tuckasegee River, in Jackson County, North Carolina. There are 23.15 acres of United States Forest Service land (Nantahala National Forest) within the boundary of the project.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* John C. Wishon, Nantahala Area Relicensing Project Manager, Duke Power, 301 NP&L Loop, Franklin, NC 28734, (828) 369–4604, *jcwishon@duke-energy.com.*

i. *FERC Contact:* Carolyn Holsopple at (202) 502–6407 or *carolyn.holsopple@ferc.gov.*

j. Deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, 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.

Comments, recommendations, terms and conditions, 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 existing East Fork Project operates in a peaking mode and is comprised of three developments: Cedar Cliff, Bear Creek and Tennessee Creek. The Cedar Cliff development consists of the following features: (1) A 590-foot-long, 173-foot-tall earth core and rockfill dam (Cedar Cliff Dam); (2) a service spillway excavated in rock at the right abutment; (3) a 221-foot-long emergency spillway located at the left abutment; (4) a 121-acre reservoir, with a normal reservoir elevation of 2,330 feet National Geodetic Vertical Datum and a storage capacity of 6,200-acre-feet; (5) a concrete powerhouse containing one generating unit having an installed capacity of 6.1 megawatts (MW); and (6) appurtenant facilities.

The Bear Creek development consists of the following features: (1) A 760-foot-long, 215-foot-tall earth core and rockfill dam (Bear Creek Dam); (2) a spillway on the right abutment; (3) a 473-acre reservoir, with a normal reservoir elevation of 2,560 feet National Geodetic Vertical Datum and a storage capacity of 34,650-acre-feet; (4) a concrete powerhouse containing one generating unit having an installed capacity of 8.2 MW; and (5) appurtenant facilities.

The Tennessee development consists of the following features: (1) A 385-foot-long, 140-foot-tall earth core and rockfill dam (Tanasee Creek Dam) with a 225-foot-long, 15-foot-tall earth and rockfill saddle dam located 600 feet south of the Tanasee Creek Dam left abutment; (2) a spillway located in a channel excavated in the right abutment; (3) a 810-foot-long, 175-foot-tall earth core and rockfill dam (Wolf Creek Dam); (4) a spillway

located in a channel excavated in the right abutment; (5) a 40-acre reservoir (Tanasee Creek Lake), with a normal reservoir elevation of 3,080 feet National Geodetic Vertical Datum and a storage capacity of 1,340-acre-feet; (6) a 176-acre reservoir (Wolf Creek Lake), with a normal reservoir elevation of 3,080 feet National Geodetic Vertical Datum and a storage capacity of 10,040-acre-feet; (7) a concrete powerhouse containing one generating unit having an installed capacity of 8.75 MW.

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.

You may also 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. Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

All filings must (1) bear in all capital letters the title ''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 submitting the filing; 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. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

Magalie R. Salas,

Secretary.

[FR Doc. E5–336 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Surrender of License andSoliciting Comments, Motions To Intervene, and Protests

January 19, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Surrender of License.

b. *Project No.:* 8535–039.

c. *Date filed:* December 20, 2004.

d. *Licensee:* Virginia Hydrogeneration and Historical Society, LC.

e. *Name of Project:* Battersea Dam.

f. *Location:* Located on the Appomattox River, in Chesterfield and Dinwiddie Counties, Virginia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Licensee Contact:* Paul V. Nolan, Esq., 5515 North 17th Street, Arlington, Virginia 22205, (703) 534–5509.

i. *FERC Contact:* Regina Saizan, (202) 502–8765.

j. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, and recommendations for terms and conditions.

k. *Deadline for filing responsive documents:* comments, motions to intervene, protests, and recommendations for terms and conditions concerning the application shall be filed with the Commission by February 22, 2005. All reply comments must be filed with the Commission by March 7, 2005.

Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in 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, the intervenor must also serve a copy of the document on that resource agency.

l. *Description of Proposed Action:* The licensee seeks to surrender the license because its lease of the project lands and facilities has been cancelled and it does not have the means or the intent to reacquire the project lands and to operate the project. The 500 kilowatt project is currently not operating.

m. *Locations of Application:* A copy of the application is available for inspection and reproduction at the Commission in the Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, here P–8535, in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h. above.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene:* 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, 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.

p. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''REPLY COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and eight copies to: Magalie

R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to the Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

q. *Agency Comments:* Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If any agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. E5–341 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice Soliciting Comments, and Final Recommendations, Terms and Conditions, and Prescriptions

January 19, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2150–033.

c. *Date Filed:* April 30, 2004.

d. *Applicant:* Puget Sound Energy.

e. *Name of Project:* Baker River Hydroelectric Project.

f. *Location:* On the Baker River, near the Town of Concrete, in Whatcom and Skagit Counties, Washington. The project occupies about 5,207 acres of lands within the Mt. Baker-Snoqualmie National Forest managed by the U.S. Forest Service.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)—825(r).

h. *Applicant Contact:* Connie Freeland, Puget Sound Energy, P.O. Box 97034 PSE–09S Bellevue, WA 98009–9734; (425) 462–3556 or connie.freeland@pse.com.

i. *FERC Contact:* Steve Hocking, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426; (202) 502–8753 or *steve.hocking@ferc.gov*

j. Deadline for filing comments and final recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please put the project name ''Baker River Project'' and project number ''P–2150–033'' on the first page of all documents.

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.

Comments and final recommendations, terms and conditions, 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.

l. *Project Description:* The Baker River Project has two developments. The Upper Baker development consists of the following existing facilities: (1) A 312-foot-high by 1,200-foot-long concrete gravity dam impounding Baker Lake with a surface area of about 4,980 acres at a normal full pool elevation of 727.77 feet mean sea level (msl); (2) a 122-foot-long, 59-foot wide concrete and steel powerhouse at the base of the dam containing two turbine-generator units, Unit No. 1 with an authorized capacity of 52,400 kilowatts (kW) and Unit No. 2 with an authorized capacity of 38,300 kW; (3) a 115-foot-high by 1,200-foot-long earth and rock-fill dam, known as West Pass dike, located in a depression about 1,500 feet north of Upper Baker dam; (4) a 22-foot-high by 3,000-foot-long earth-filled dike, known as Pumping Pond dike, which impounds Depression Lake with a surface area of 44 acres at a normal full pool elevation of 699 feet msl; (5) a water recovery pumping station adjacent to Pumping Pond; (6) fish passage facilities and fish spawning facilities; and (7) appurtenant facilities.

The Lower Baker development consists of the following existing facilities: (1) A 285-foot-high by 550-foot-long concrete thick arch dam impounding Lake Shannon with a surface area of about 2,278 acres at a normal full pool elevation of 442.35 feet msl; (2) a concrete intake equipped with trashracks and gatehouse located at the dam's left abutment; (3) a 1,410-foot-long concrete and steel-lined pressure tunnel; (4) a concrete surge tank near the downstream end of the pressure tunnel; (5) a 90-foot-long, 66-foot-wide concrete and steel powerhouse containing one turbine-generator unit, Unit No. 3 with an authorized capacity of 79,330 kW; (6) a 750-foot-long, 115-kilovolt transmission line; (7) fish passage facilities including a 150-foot-long by 12-foot-high barrier dam; and (8) appurtenant facilities.

m. A copy of the application is available for review in the Commission's Public Reference Room or may be viewed on the Commission's Web site *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.

n. All filings must (1) bear in all capital letters the title ''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 submitting the filing; 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. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

You may register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects.

For assistance, contact FERC Online Support.

o. *Revised Procedural Schedule:* The application will be processed according to the following Revised Hydro Licensing Schedule:

Amended PDEA and Draft Biological Assessment Due: January 31, 2005.

Final Terms and Conditions Due: March 21, 2005.

Last Day to Request Water Quality Certificate: March 21, 2005.

Issue Notice of Draft Environmental Assessment (EA): May 2005.

Issue Notice of Final EA: August 2005.

Ready for Commission Decision on Application: December 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–346 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application and Soliciting Comments, Motions To Intervene, and Protests

January 19, 2005.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-project use of project lands.

b. *Project No:* 739–017.

c. *Date Filed:* January 3, 2005.

d. *Applicant:* Appalachian Power Company.

e. *Name of Project:* Claytor Hydroelectric Project.

f. *Location:* The project is located on the New River in Pulaski County, Virginia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Theresa P. Rogers, Hydro Generation Department, American Electric Power, P.O. Box 2021, Roanoke, Virginia 24022–2121, (540) 985–2441.

i. *FERC Contact:* Any questions on this notice should be addressed to Jean Potvin at (202) 502–8928, or by e-mail: *jean.potvin@ferc.gov.*

j. *Deadline for Filing Comments and/or Motions:* February 22, 2005.

All documents (original and eight copies) should be filed with: Ms. Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, DHAC, PJ–12.1, 888 First Street, NE., Washington DC 20426. Please include the project number (739–017) on any comments or motions filed. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

k. *Description of Proposal:* Appalachian Power Company, licensee for the Claytor Project, proposes to grant permission to Conrad Brothers Marina to modify and expand its marina facilities to include: (1) The removal of 18 enclosed boathouses; (2) the installation of 2 stationary, covered boat docks with 15 slips each; and (3) the installation of 6 floating docks slips with 6 slips each for a total addition of 30 covered, stationary boat slips and 36 floating slips at the marina. Existing facilities include a boat ramp, gasoline dispensing facility, one stationary dock with 11 covered slips and 5 existing floating docks with a total of 66 floating slips.

l. This filing 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 call toll-free 1–866–208–3676, or for TTY, call (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* 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, 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.

o. *Filing and Service of Responsive Documents:* Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments:* Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. E5–347 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR00–9–004]

Gulfterra Texas Pipeline, LP; Notice of Technical Conference

January 21, 2005.

Take notice that a technical conference will be held on Thursday, January 27, 2005, at 10 a.m. (EST), in a room to be designated at the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The conference will address questions related to the July 12, 2004, filing by Gulfterra Texas Pipeline, LP, to comply with the June 11, 2002, Order on Staff Panel and the February 25, 2004, Order on Rehearing and Denying Late Intervention.

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or 202–208–1659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

All interested parties and staff are permitted to attend.

Magalie R. Salas,

Secretary.

[FR Doc. E5–330 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–13–000]

Ingleside Energy Center LNG Project; Notice of Technical Conference

January 21, 2005.

On Tuesday, February 8, 2005, at 8:30 a.m. (CST), staff of the Office of Energy Projects will convene a cryogenic design and technical conference regarding the proposed Ingleside Energy Center LNG import terminal. The cryogenic conference will be held in the Sheraton North Houston at George Bush Intercontinental Airport. The hotel is located at 15700 John F. Kennedy Boulevard, Houston, Texas 77032. For hotel details call 281–442–5100.

In view of the nature of the critical energy infrastructure information and security issues to be explored, the cryogenic conference will not be open to the public. Attendance at this conference will be limited to existing parties to the proceeding (anyone who has specifically requested to intervene as a party) and to representatives of interested federal, state, and local agencies. Any person planning to attend the February 8th cryogenic conference *must register* by close of business on Friday, February 4th , 2005. Registrations may be submitted either online at *http://www.ferc.gov/whats-new/registration/cryo-conf-form.asp* or by faxing a copy of the form (found at the referenced online link) to 202–208–0353. All attendees must sign a non-disclosure statement prior to entering the conference. Upon arrival at the hotel, check the reader board in the hotel lobby for venue. For additional information regarding the cryogenic conference, please contact Thach Nguyen at 202–502–6364.

Magalie R. Salas,

Secretary.

[FR Doc. E5–340 Filed 1–28–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL –7865–4]

Science Advisory Board Staff Office; EPI Suite Review Panel of the Science Advisory Board; Request for Nominations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office (hereinafter, the ''Staff Office'') is announcing the formation of a new SAB review panel known as the EPI Suite Review Panel of the Science Advisory Board (hereinafter, the ''Panel'') and is hereby soliciting nominations for this Panel.

DATES: Nominations should be submitted by February 22, 2005, per the instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Request for Nominations may contact Ms. Kathleen White, Designated Federal Officer (DFO), EPA Science Advisory Board Staff, at telephone/voice mail: (202) 343–9878; or via e-mail at: *white.kathleen@epa.gov.* General information concerning the SAB can be found on the EPA Web site at: *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background: A mission of the U.S. EPA's Office of Pollution Prevention and Toxics (OPPT) is to evaluate potential risks of commercial chemical substances that are or will be released to the environment. OPPT also has the primary responsibility for implementing Agency policy on pollution prevention (P2), and in this role is a critical provider of information and guidance to risk assessors and risk managers. The understanding of and ability to predict the behavior of a chemical substance in a biological or environmental system depends upon knowledge of the physical, chemical and environmental properties of that substance. Accordingly, OPPT has supported the development of software for estimating these properties from chemical structure known as the Estimation Programs Interface (EPI) suite. EPI Suite is routinely used in evaluating new chemicals under EPA's Premanufacture Notices (PMNs) for new chemicals under section 5 of the Toxic Substances Control Act, and is widely used for predicting physical/chemical properties and environmental fate and transport properties for chemicals already in commerce. Further information about EPI Suite and its applications can be found at: *http://www.epa.gov/opptintr/exposure/docs/episuite.htm.* OPPT has requested that the EPA Science Advisory Board (SAB) review the supporting science, functionality, and appropriate use of EPI Suite.

The SAB's mission, as established by 42 U.S.C. 4365, is to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical bases for EPA policies and regulations. In response to OPPT's request, the SAB will form a review panel to conduct a review of the EPI Suite. The EPI Suite Review Panel will provide advice through the chartered SAB. The Panel will provide advice regarding the comprehensiveness and soundness of the science supporting EPI Suite including method validation, alternative estimation methods, completeness of the software, documentation, and appropriateness of its current applications. The Panel will consider both appropriate use in the PMN program and other uses in screening level assessments. The work of this panel is expected to continue until the review is complete. The EPI Suite Review Panel will comply with the openness provisions of the Federal Advisory Committee Act (FACA) and all appropriate SAB procedural policies, including the SAB process for panel formation described in the *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board,* which can be found on the SAB's Web site at: *http://www.epa.gov/sab/pdf/ec0210.pdf.*

Request for Nominations: The SAB Staff Office is requesting nominations of recognized scientists and engineers with expertise in one or more of the following areas:

(1) Environmental chemistry and engineering;

(2) Pollution prevention, especially experience deciding whether or not to go into production with a chemical;

(3) Development of estimation models, such as QSARs that predict properties, effects and fate of chemicals from structure; and

(4) Application of EPI Suite or similar tools.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate individuals qualified in any of the areas of expertise described above to serve on the Panel. Nominations should be submitted in electronic format through the *Form for Nominating Individuals to Panels of the EPA Science Advisory Board* provided on the SAB Web site. The form can be accessed through a link on the blue navigational bar on the SAB Web site, *http://www.epa.gov/sab.* To be considered, all nominations must include the information required on that form.

Anyone who is unable to submit nominations electronically using this form, or who has questions concerning the nomination process may contact Ms. Kathleen White, DFO, as indicated

above in this notice. Nominations should be submitted in time to arrive no later than February 22, 2005. Any questions concerning either this process or any other aspects of this notice should be directed to the DFO.

To be considered, all nominations must include: (a) A current biography, *curriculum vitae* (C.V.) or resume, which provides the nominee's background, experience and qualifications for the Committee; and (b) a brief biographical sketch (''biosketch''). The biosketch should be no longer than one page and must contain the following information for the nominee:

(i) Current professional affiliations and positions held;

(ii) Area(s) of expertise, and research activities and interests;

(iii) Leadership positions in national associations or professional publications or other significant distinctions;

(iv) Educational background, especially advanced degrees, including when and from which institutions these were granted;

(v) Service on other advisory committees, professional societies, especially those associated with issues under discussion in this review; and

(vi) Sources of recent (*i.e.*, within the preceding two years) grant and/or other contract support, from government, industry, academia, etc., including the topic area of the funded activity. Please note that even if there is no responsive information (*e.g.*, no recent grant or contract funding), this must be indicated on the biosketch (by ''N/A'' or ''None''). Incomplete biosketches will result in nomination packages not being accepted.

The EPA SAB Staff Office will acknowledge receipt of the nomination. After considering the nominees (termed the ''Widecast''), the SAB Staff Office will identify a subset (known as the ''Short List'') for more detailed consideration. Criteria used by the Staff Office in developing this Short List are given at the end of the following paragraph. The Short List will be posted on the SAB Web site at: *http://www.epa.gov/sab*, and will include the nominees' names and their biosketches. Public comments will be accepted for 21 calendar days on the Short List. During this comment period, the public may provide information, analysis or other documentation on nominees that the Staff Office should consider in evaluating candidates for the Panel.

For the EPA SAB Staff Office, a balanced Panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. Public responses to the Short List candidates will be considered in the selection of the Panel, along with information provided by candidates and information independently-gathered by the SAB Staff Office on the background of each candidate (*e.g.*, financial disclosure information and computer searches to evaluate a nominee's prior involvement with the topic under review). Specific criteria to be used in evaluating an individual Panel member include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) scientific credibility and impartiality; and (e) skills working in advisory committees, subcommittees and review panels.

Short List candidates must submit the ''Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency'' (EPA Form 3110–48). This confidential form allows Government officials to determine whether there is a statutory conflict between that person's public responsibilities (which includes membership on an EPA Federal advisory committee) and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded from the following URL address: *http://www.epa.gov/sab/pdf/epaform3110–48.pdf.*

In addition to reviewing background material, Panel members will be asked to attend one public face-to-face meeting over the anticipated course of the advisory activity.

Dated: January 21, 2005.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 05–1716 Filed 1–28–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7865–5]

Science Advisory Board Staff Office; Notification of Advisory Meetings of the Science Advisory Board Radiation Advisory Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Science Advisory Board (SAB) Radiation Advisory Committee (RAC) will receive briefings from the Agency and discuss its advisory agenda for FY 2005.

DATES: February 28, 2005. The SAB RAC will meet on February 28, 2005, via teleconference from 10 a.m. to 1 p.m. eastern standard time.

LOCATION: The public teleconference meeting will take place via teleconference only.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to obtain the teleconference call-in number and access codes; would like to submit written or brief oral comments (3 minutes or less); or who wants further information concerning this public meeting should contact Dr. Jack Kooyoomjian, Designated Federal Officer (DFO), EPA SAB, 1200 Pennsylvania Avenue, NW. (MC 1400F), Washington, DC 20460; via telephone/voice mail: (202) 343–9984; fax: (202) 233–0643; or e-mail at: *kooyoomjian.jack@epa.gov*. General information concerning the SAB can be found on the EPA Web site at: *http://www.epa.gov/sab*.

SUPPLEMENTARY INFORMATION:

Background and Purpose: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, the SAB Staff Office hereby gives notice of a public meeting of the Radiation Advisory Committee (RAC). The EPA Office of Radiation and Indoor Air (ORIA) requested the SAB to provide advice on the National Monitoring System (NMS) upgrade, formerly known as the Environmental Radiation Ambient Monitoring System (ERAMS). The RAC will receive briefings from ORIA about this request and discuss its plan for the coming year.

Availability of Meeting Materials: Copies of the agenda for the SAB meetings described in this notice will be posted on the SAB Web site at: *http://www.epa.gov/sab* prior to the meeting. Persons who wish to obtain background materials on the current ERAMS network may find them at the following Web site: *http://www.epa.gov/narel/erams/index.html*. For copies of the EPA/ORIA briefing materials on the NMS, please contact Dr. Mary E. Clark of the U.S. EPA, Office of Radiation and Indoor Air (Mail Code 6601J), by telephone/voice mail at (202)-343–9348, by fax at (202)-343–2395; or via e-mail at *clark.marye@epa.gov*.

Providing Oral or Written Comments at SAB Meetings: It is the policy of the SAB Staff Office to accept written public comments of any length, and to

accommodate oral public comments wherever possible. The SAB Staff Office expects the public statements presented at its meetings will not be repetitive of previously-submitted oral or written statements.

Oral Comments: In general, each individual or group requesting an oral presentation at a conference call meeting will be limited to a total time of three minutes (unless otherwise indicated). Requests to provide oral comments must be *in writing* (e-mail, fax, or mail) and received by the DFO no later than noon eastern time five business days prior to the meeting in order to reserve time on the meeting agenda. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting.

Written Comments: Although the SAB Staff Office accepts written comments until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office no later than noon eastern time five business days prior to the meeting so that the comments may be made available to the Panelists for their consideration. Comments should be supplied to the DFO (preferably by e-mail) at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 98/2000/XP format)). Those providing written comments and who attend the meeting are also asked to bring 35 copies of their comments for public distribution.

Meeting Access: Individuals requiring special accommodation at this meeting should contact the DFO at the phone number or e-mail address noted above at least five business days prior to the meeting, so that appropriate arrangements can be made.

Dated: January 21, 2005.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 05–1717 Filed 1–28–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7865–6]

Science Advisory Board Staff Office; Notification of Upcoming Science Advisory Board Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public meeting of the EPA Science Advisory Board (the Board) to discuss the EPA science and research programs and budget, and to conduct other Board activities.

ADDRESSES: The meeting of the Science Advisory Board will be held in the Polaris Room of the Ronald Reagan Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20004.

DATES: February 17–18, 2005. A public meeting of the Board will be held from 8:30 a.m. to 5:30 p.m. on February 17 and 18, 2005 (eastern time).

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain further information regarding the SAB may contact Mr. Thomas O. Miller, Designated Federal Officer (DFO), U.S. EPA Science Advisory Board Staff Office (1400F), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; by telephone/voice mail at (202) 343–9982; or via e-mail at *miller.tom@epa.gov.* The SAB Mailing address is: U.S. EPA, Science Advisory Board (1400F), 1200 Pennsylvania Ave., NW., Washington, DC 20460. General information about the SAB, as well as any updates concerning the meeting announced in this notice, may be found in the SAB Web site at: *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background: The Science Advisory Board (SAB) was established by 42 U.S.C. 4365 to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. At this meeting, the SAB will focus on EPA's science and research programs included within the FY 2006 budget proposal. Evaluating and advising the EPA Administrator on the Agency science and research program budget is an annual activity of the Science Advisory Board. At this meeting, the SAB may also conduct a review of one or more draft committee or panel reports that are being sent to it for approval prior to delivery to the U.S. EPA Administrator. Any such reviews will be announced on the above mentioned SAB Web site at least one week prior to the meeting.

For the Science and Research Advisory, the SAB will receive briefings by representatives from various EPA organizations on the science and research programs that are to be conducted under the FY 2006 EPA budget request; members and EPA representatives will discuss how these programs relate to and move forward from existing programs; and the members will then deliberate on the advice they will provide to the Administrator. The final agreed upon Charge to the Board will be placed onto the SAB Web site prior to this meeting.

Availability of Review Material for the Board Meeting: Documents that are the subject of this meeting are available from the SAB Staff Office Web site *http://www.epa.gov/sab/.*

Procedures for Providing Public Comment: It is the policy of the EPA Science Advisory Board (SAB) Staff Office to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA SAB Staff Office expects that public statements presented at Board meetings will not be repetitive of previously submitted oral or written statements.

Oral Comments: In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes (unless otherwise indicated). For conference call meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Interested parties should contact the Designated Federal Official (DFO) in writing via e-mail at least one week prior to the meeting in order to be placed on the public speaker list for the meeting. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the participants and public at the meeting.

Written Comments: Although written comments are accepted until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 98/2000/XP format). Those providing written comments and who attend the meeting are also asked to bring 35 copies of their comments for public distribution.

Meeting Accommodations: Individuals requiring special accommodation to access these meetings, should contact the relevant DFO at least five business days prior to

the meeting so that appropriate arrangements can be made.

Dated: January 24, 2005.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 05–1718 Filed 1–28–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

Docket Number ORD–2005–0005 [FRL–7865–7]

Board of Scientific Counselors, Ecological Research Subcommittee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, the Environmental Protection Agency, Office of Research and Development (ORD), announces three meetings of the Board of Scientific Counselors (BOSC) Ecological Research Subcommittee.

DATES: Two teleconference call meetings will be held, the first on Thursday, February 17, 2005, from 3 a.m. to 5:30 p.m., and the second on Thursday, March 3, 2005, from 3 to 5:30 p.m. A face-to-face meeting will be held beginning Monday, March 7, 2005 (8:30 a.m. to 5:30 p.m.), continuing on Tuesday, March 8, 2005 (8:30 a.m. to 5:30 p.m.), and concluding on Wednesday, March 9, 2005 (8:30 a.m. to 5 p.m.). All times noted are Eastern Standard Time. Meetings may adjourn early if all business is completed.

ADDRESSES: *Conference calls:* Participation in the conference calls will be by teleconference only—meeting rooms will not be used. Members of the public may obtain the call-in number and access code for the teleconference meeting from Greg Susanke, whose contact information is listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. *Face-to-Face Meeting:* The face-to-face meeting will be held at the U.S. EPA Research Triangle Park (RTP) Campus, National Computer Center Building (Room N110), located at 109 T.W. Alexander Drive, Research Triangle Park, NC 27711.

Document Availability

Draft agendas for the meetings are available from Greg Susanke, whose contact information is listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Requests for the draft agendas will be accepted up to 2 business days prior to each conference call/meeting date. The draft agendas also can be viewed through EDOCKET, as provided in Unit I.A. of the **SUPPLEMENTARY INFORMATION** section.

Any member of the public interested in making an oral presentation at one of the conference calls or at the face-to-face meeting may contact Greg Susanke, whose contact information is listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Requests for making oral presentations will be accepted up to 2 business days prior to each conference call/meeting date. In general, each individual making an oral presentation will be limited to a total of three minutes.

Submitting Comments

Written comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I.B. of this section. Written comments will be accepted up to 2 business days prior to each conference call/meeting date.

FOR FURTHER INFORMATION CONTACT: Greg Susanke, Designated Federal Officer, Environmental Protection Agency, Office of Research and Development, Mail Code 8104R, 1200 Pennsylvania Avenue NW., Washington, DC; telephone (202) 564–9945; fax (202) 565–2925; e-mail *susanke.greg@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

This notice announces three meetings of the BOSC Ecological Research Subcommittee. The purpose of the meetings are to evaluate EPA's Ecological Research Program. Proposed agenda items for the conference calls include, but are not limited to: charge questions, objective of program reviews, background on the U.S. EPA's Ecological Research Program, writing assignments, and planning for the face-to-face meeting. Proposed agenda items for the face-to-face meeting include, but are not limited to: presentations by key EPA staff involved in the Ecological Research Program, poster sessions on ORD's Ecological research, and preparation of the draft report. The conference calls and the face-to-face meeting are open to the public.

Information on Services for the Handicapped: Individuals requiring special accommodations at this meeting should contact Greg Susanke, Designated Federal Officer, at (202) 564–9945 at least five business days prior to the meeting so that appropriate arrangements can be made to facilitate their participation.

A. How Can I Get Copies of Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. ORD–2005–0005. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Documents in the official public docket are listed in the index in EPA's electronic public docket and comment system, EDOCKET. Documents are available either electronically or in hard copy. Electronic documents may be viewed through EDOCKET. Hard copies of the draft agendas may be viewed at the Board of Scientific Counselors, Ecological Research Subcommittee Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the ORD Docket is (202) 566–1752.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EDOCKET. You may use EDOCKET at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number (ORD–2005–0005).

For those wishing to make public comments, it is important to note that EPA's policy is that comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks mailed or delivered to the docket will be transferred to EPA's electronic public docket. Written public comments mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket.

B. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number (ORD–2005–0005) in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment, and it allows EPA to contact you if further information on the substance of the comment is needed or if your comment cannot be read due to technical difficulties. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment placed in the official public docket and made available in EPA's electronic public docket. 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.

i. *EDOCKET.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EDOCKET at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, *www.epa.gov*, select ''Information Sources,'' ''Dockets,'' and ''EDOCKET.'' Once in the system, select ''search,'' and then key in Docket ID No. ORD–2005–0005. The system is an anonymous access system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by electronic mail (e-mail) to *ORD.Docket@epa.gov*, Attention Docket ID No. ORD–2005–0005. In contrast to EPA's electronic public docket, EPA's e-mail system is not an anonymous access system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM mailed to the mailing address identified in Unit I.B.2. These electronic submissions will be accepted in Word, WordPerfect or rich text files. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send your comments to: U.S. Environmental Protection Agency, ORD Docket, EPA Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. ORD–2005–0005.

3. *By Hand Delivery or Courier.* Deliver your comments to: EPA Docket Center (EPA/DC), Room B102, EPA West Building, 1301 Constitution Avenue, NW., Washington, DC, Attention Docket ID No. ORD–2005–0005 (note: this is not a mailing address). Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.A.1.

Dated: January 25, 2005.

Kevin Y. Teichman,

Director, Office of Science Policy.

[FR Doc. 05–1719 Filed 1–28–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7865–8]

Draft Air Quality Criteria for Ozone and Related Photochemical Oxidants E-Docket No. ORD–2004–0015

AGENCY: Environmental Protection Agency.

ACTION: Notice of first external review draft for public review and comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) Office of Research and Development's National Center for Environmental Assessment (NCEA) is reviewing and, as appropriate, revising the EPA document, *Air Quality Criteria for Ozone and Related Photochemical Oxidants*, EPA–600/AP–93/004aF–cF, published in 1996. Today's **Federal Register** notice announces the availability of a first external review draft of the revised ozone air quality criteria document (AQCD).

DATES: The ninety-day period for submission of comments on the first external review draft of the revised Ozone AQCD begins January 31, 2005, and ends May 2, 2005.

ADDRESSES: The first external review draft of the revised Ozone AQCD will be available on or about January 31, 2005. Internet users will be able to download a copy of this document from the NCEA home page. The URL is *http://www.epa.gov/ncea/*. A limited number of CD–ROM or paper copies will be available. Contact Ms. Diane Ray by phone (919–541–3637), fax (919–541–1818), or e-mail (*ray.diane@epa.gov*) to request either of these. Please provide the draft document's title, *Air Quality Criteria for Ozone and Related Photochemical Oxidants (First External Review Draft), Volumes I, II, and III,* EPA 600/R–05/004aA, bA, and cA, as well as your name and address, to facilitate processing of your request. Public comments on the first external review draft of the revised Ozone AQCD may be submitted electronically, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions as provided in the section of this notice entitled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: For details on the period for submission of comments from the public, contact the Office of Environmental Information Docket; telephone: 202–566–1752; facsimile: 202–566–1753; or e-mail: *ORD.Docket@epa.gov*.

For technical information, contact Robert Elias, Ph.D., NCEA, facsimile: 919–541–1818, or e-mail: *elias.robert@epa.gov*.

SUPPLEMENTARY INFORMATION: Section 108 (a) of the Clean Air Act directs the EPA Administrator to identify certain pollutants which ''may reasonably be anticipated to endanger public health and welfare'' and to issue air quality criteria for them. These air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air * * *'' Under section 109 of the Act, EPA is then to establish National Ambient Air Quality Standards (NAAQS) for each pollutant for which EPA has issued criteria. Section 109 (d) of the Act subsequently requires

periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health and welfare. EPA is also to revise the NAAQS, if appropriate, based on the revised criteria.

Ozone is one of six ''criteria'' pollutants for which EPA has established air quality criteria and NAAQS. On September 26, 2000 (65 FR 57810), EPA formally initiated its current review of the criteria and NAAQS for ozone, requesting the submission of recent scientific information on specified topics. Preliminary outlines for the proposed chapters were presented in the draft Project Work Plan that was released for public comment (66 FR 67524, December 31, 2001) and for review by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (68 FR 3527, January 24, 2003). Later in 2003, a series of workshops were convened to discuss draft sections and chapters for revising the existing Ozone AQCD (68 FR 17365, April 9, 2003 and 68 FR 60369, October 22, 2003).

After the end of the comment period on the *Air Quality Criteria for Ozone and Related Photochemical Oxidants (First External Review Draft)*, EPA will present the draft at a public meeting for review by the Clean Air Scientific Advisory Committee (CASAC). Public comments received will be provided to the CASAC review panel. There will be a **Federal Register** notice to inform the public of the exact date and time of that CASAC meeting.

How To Submit Comments to EPA's E-Docket

EPA has established an official public docket for information pertaining to the revision of the Ozone AQCD, Docket ID No. ORD–2004–0015. The official public docket is the collection of materials, excluding Confidential Business Information (CBI) or other information whose disclosure is restricted by statute, that is available for public viewing at the Office of Environmental Information (OEI) Docket in the Headquarters EPA Docket Center, EPA West Building, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202–566–1744, and the telephone number for the OEI Docket is 202–566–1752; facsimile: 202–566–1753; or e-mail: *ORD.Docket@epa.gov*.

An electronic version of the official public docket is available through EPA's electronic public docket and comment system, E-Docket. You may use E-Docket at *http://www.epa.gov/edocket/* to submit or view public comments, to access the index listing of the contents of the official public docket, and to view those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in E-Docket. Information claimed as CBI and other information with disclosure restricted by statute, also not included in the official public docket, will not be available for public viewing in E-Docket. Copyrighted material also will not be placed in E-Docket but will be referenced there and available as printed material in the official public docket.

Persons submitting public comments should note that EPA's policy makes the information available as received and at no charge for public viewing at the EPA Docket Center or in E-Docket. This policy applies to information submitted electronically or in paper form, except where restricted by copyright, CBI, or statute.

Unless restricted as above, public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to E-Docket. Physical objects will be photographed, where practical, and the photograph will be placed in E-Docket along with a brief description written by the docket staff.

You may submit public comments electronically, by mail, by facsimile, or by hand delivery/courier. To ensure proper receipt by EPA, include the appropriate docket identification number with your submission. Please adhere to the specified submitting period. Public comments received or submitted past the closing date will be marked ''late'' and may only be considered if time permits.

If you submit public comments electronically, EPA recommends that you include your name, mailing address, and an e-mail address or other details for contacting you. Also include these contact details on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the person submitting the public comments and allows EPA to contact you in case the Agency cannot read what you submit due to technical difficulties or needs to clarify issues raised by what you submit. If EPA cannot read what you submit due to technical difficulties and cannot contact you for clarification, it may delay or prohibit the Agency's consideration of the public comments.

To access EPA's electronic public docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''search,'' and key in Docket ID No. ORD–2004–0015. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact details if you are merely viewing the information.

Public comments may be sent by electronic mail (e-mail) to *ORD.Docket@epa.gov*, Attention Docket ID No. ORD–2004–0015. In contrast to EPA's electronic public docket, EPA's e-mail system is *not* an ''anonymous access'' system. If you send an e-mail directly to the docket without going through EPA's E-Docket, EPA's e-mail system automatically captures your e-mail address, and it becomes part of the information in the official public docket and is made available in EPA's E-Docket.

You may submit public comments on a disk or CD ROM mailed to the OEI Docket mailing address. Files will be accepted in WordPerfect, Word, or PDF file format. Avoid the use of special characters and any form of encryption.

If you provide public comments in writing, please submit one unbound original, with pages numbered consecutively, and three copies. For attachments, provide an index, number pages consecutively with the main text, and submit an unbound original and three copies.

Dated: January 25, 2005.

Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. 05–1720 Filed 1–28–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Bank or Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 05-1047) published on page 3202 of the issue for January 21, 2005.

Under the Federal Reserve Bank of Atlanta heading, the entry for Ghomeshi Mohammad Mehdi, Miami, Florida, is revised to read as follows:

A. Federal Reserve Bank of Atlanta (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. Mohammad Mehdi Ghomeshi, Miami, Florida; to acquire voting shares of Great Financial Corporation, Miami Lakes, Florida, and thereby indirectly acquire voting shares of Great Florida Bank, Miami, Florida.

Comments on this application must be received by February 2, 2005.

Board of Governors of the Federal Reserve System, January 25, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–1666 Filed 1–28–05; 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 application 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 February 25, 2005.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. Community Bancshares of Mississippi, Inc., Employee Stock Ownership Plan, Brandon, Mississippi; to become a bank holding company by acquiring 58.6 percent of the voting shares of the Community Bancshares of Mississippi, Inc., Brandon, Mississippi; and First National Bank of Lucedale, Lucedale, Mississippi; Community Bank of Mississippi, Forest, Mississippi; Community Bank, Ellisville, Mississippi, Ellisville, Mississippi; Community Bank, Amory, Mississippi; Community Bank, Indianola, Mississippi, Indianola, Mississippi; Community Bank, Coast, Biloxi, Mississippi; Community Bank, Desoto County, Southaven, Mississippi; and Community Bank, Meridian, Mississippi, Meridian, Mississippi.

2. Remo Duquoin LLC, Privee LLC, and Privee Financial, Inc., all of Miami, Florida; to acquire 100 percent of the voting shares of Sequoia National Bank, San Francisco, California.

Board of Governors of the Federal Reserve System, January 25, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–1664 Filed 1–28–05; 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 February 15, 2005.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Community First Bancshares, Inc., Harrison, Arkansas; to retain voting shares of Mobius Technology Consulting, LLC, Springfield, Missouri, and thereby engage in data processing and management consulting activities, pursuant to sections 225.28(b)(9)(i)(A) and (b)(14)(i) respectively of Regulation Y.

Board of Governors of the Federal Reserve System, January 25, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–1665 Filed 1–28–05; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05AZ]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5976 or send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is 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. Written comments should be received within 60 days of this notice.

Proposed Project

A Library Of Participant Questions To Be Used In Exposure Investigation Questionnaires—New—The Agency for Toxic Substances and Disease Registry (ATSDR).

ATSDR is mandated pursuant to the 1980 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and its 1986 Amendments, the Superfund Amendments and Reauthorization Act (SARA) to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances in the environment. Exposure Investigations are an approach developed by ATSDR that employs targeted biologic and environmental sampling to assist ATSDR to better characterize past, current, and possible future human exposures to hazardous substances in the environment. The purpose of Exposure Investigations is to determine in a timely manner whether community residents are being exposed to chemical contaminants at levels that might affect their health. Exposure Investigations are usually requested by officials of a state health agency, county health departments, the Environmental Protection Agency, the general public, and ATSDR staff.

During an Exposure Investigation ATSDR conducts biomarker testing or environmental testing or both. Biomarkers may be sampled in urine, blood, or hair. Environmental samples (*e.g.*, air, water, soil, or food) can be taken from the environment where people live, spend leisure time, or other places they might come into contact with contaminants under investigation. In addition to the suspected environmental exposure source being investigated, additional exposure to the contaminant may come from other sources encountered in daily activities such as jobs, hobbies, household products, lifestyle, medicines, and foods.

To assist in interpreting the sampling results, a survey questionnaire appropriate to the specific contaminant will be administered to participants. Only a limited number of questions pertinent to exposure routes of the contaminant of concern will be administered in an investigation. Questions will be asked about the presence or absence of a specific exposure and an estimate of its extent and duration. Exposure to other sources of the contaminant of concern will also be queried in the survey. The information gathered in the survey will allow ATSDR to more accurately interpret its testing results and determine a likely source of elevated biomarker tests.

Questionnaires will generally be administered face-to-face and occasionally by phone or mail. Typically, ATSDR conducts between 10–15 exposure investigations nationally each year that would require a questionnaire. The number of participants per investigation ranges from 10 to less than 50.

ATSDR is seeking approval for a set of 40–43 potential questions. Of these, approximately 12–15 questions about the pertinent environmental pathways in an Exposure Investigation will be used. This number can vary depending on the number of contaminants being investigated, the route of exposure (breathing, eating, touching), and a number of other sources (*e.g.*, products, jobs) of the chemical(s). We will also collect general information (*e.g.*, name, address,) necessary to conduct the investigation; there are approximately 28 questions that will collect demographic information. There are no costs to respondents other than their time.

Topic areas for the complete set of questions include the following:

(1) Media specific which includes: air (indoor/outdoor); water (water source and plumbing); soil, and food (gardening, fish, game, domestic animals).

(2) Other sources such as: occupation; hobbies; household uses or house construction; lifestyle (*e.g.*, smoking); medicines and/or health conditions, and foods.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response in hours)	Total burden (in hours)
Exposure Investigation Participants	750	1	30/60	375
Total				375

Dated: January 25, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–1713 Filed 1–28–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0441]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Food and Drug Administration Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 2, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for FDA Approval to Market a New Drug—(OMB Control Number 0910–0001)—Extension

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or 505(j) of the act is effective with respect to such drug. Section 505(b) and 505(j) of the act requires a sponsor to submit to FDA a new drug application (NDA) containing, among other things, full reports of investigations that show whether or not the drug is safe and effective for use, a full list of articles used as components in the drug, a full description of manufacturing methods, samples of the drugs required, specimens of the labeling proposed to be used, and certain patent information as applicable. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination that the product is safe and effective.

This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR 314), who apply for approval of a new drug application in order to market or to continue to market a drug.

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes introductory information about the drug as well as a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information, as described under § 314.53, be submitted with the application.

Section 314.50(i) requires that patent certification information be submitted in section 505(b)(2) applications for patents claiming the drug, drug product, method of use, or method of manufacturing.

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application.

Section 314.50(k) requires that an archival, review, and field copy of the application be submitted.

Section 314.52 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders be sent by section 505(b)(2) applicants.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the act.

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (c)(2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A). (The burden hours for § 314.80(c)(1) and (c)(2) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.80(i) establishes recordkeeping requirements for reports of postmarketing adverse drug experiences. (The burden hours for § 314.80(i) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.81(b)(1) requires that field alert reports be submitted to FDA (Form FDA 3331).

Section 314.81(b)(2) requires that annual reports be submitted to FDA (Form FDA 2252). This form has been revised as a result of the requirements in the final rule ''Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports,'' published in the **Federal Register** of October 30, 2000 (65 FR 64607). The rule describes the types of postmarketing studies covered by the status reports, the information to be included in the reports, and the type of information that FDA would consider appropriate for public disclosure. The rule implemented section 130(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The changes to the form include adding new spaces for the new status reports, reporting for biological products, and editorial changes.

Section 314.81(b)(3)(i) requires that drug advertisements and promotional labeling be submitted to FDA (Form FDA 2253).

Section 314.81(b)(3)(iii) sets forth reporting requirements for sponsors who withdraw an approved drug product from sale. (The burden hours for § 314.81(b)(3)(iii) are already approved by OMB under OMB control number 0910–0045 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.90 sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.50 through 314.81. (The information collection hour burden estimate for NDA waiver requests is included in table 1 of this document under estimates for §§ 314.50, 314.60, 314.70 and 314.71.)

Section 314.93 sets forth requirements for submitting a suitability petition in accordance with § 10.20 (21 CFR 10.20) and § 10.30. (The burden hours for § 314.93 are already approved by OMB under 0910–0183 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.94(a) and (d) requires that an ANDA contain the following information: Application form; table of contents; basis for ANDA submission; conditions of use; active ingredients; route of administration, dosage form, and strength; bioequivalence; labeling; chemistry, manufacturing, and controls; samples; patent certification.

Section 314.95 requires that notice of certification of invalidity or noninfringement of a patent to patent

holders and NDA holders be sent by ANDA applicants.

Section 314.96 sets forth requirements for amendments to an unapproved ANDA.

Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for changes that require FDA approval.

Section 314.98(a) sets forth postmarketing adverse drug experience reporting and recordkeeping requirements for ANDAs. (The burden hours for § 314.98(a) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.98(c) requires other postmarketing reports for ANDAs: Field alert reports (Form FDA 3331), annual reports (Form FDA 2252), and advertisements and promotional labeling (Form FDA 2253). (The information collection hour burden estimate for field alert reports is included in table 1 of this document under § 314.81(b)(1); the estimate for annual reports is included under § 314.81(b)(2); the estimate for advertisements and promotional labeling is included under § 314.81(b)(3)(i).)

Section 314.99(a) requires that sponsors comply with certain reporting requirements for withdrawing an unapproved ANDA and for a change in ownership of an ANDA.

Section 314.99(b) sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.92 through 314.99. (The information collection hour burden estimate for ANDA waiver requests is included in table 1 of this document under estimates for § 314.94(a) and (d) and §§ 314.96 and 314.97.)

Section 314.101(a) states that if FDA refuses to file an application, the applicant may request an informal conference with FDA and request that the application be filed over protest.

Section 314.107(c)(4) requires notice to FDA by ANDA or section 505(b)(2) application holders of any legal action concerning patent infringement.

Section 314.107(e)(2)(iv) requires that an applicant submit a copy of the entry of the order or judgment to FDA within 10 working days of a final judgment.

Section 314.107(f) requires that ANDA or section 505(b)(2) applicants notify FDA of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner may also notify FDA of the filing of any legal action for patent infringement. The patent owner or approved application holder who is an exclusive patent licensee must submit to FDA a waiver that waives the opportunity to file a legal action for patent infringement.

Section 314.110(a)(3) and (a)(4) states that, after receipt of an FDA approvable letter, an applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (The burden hours for § 314.110(a)(3) and (a)(4) are included under parts 10 through 16 (21 CFR part 16) hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document.)

Section 314.110(a)(5) states that, after receipt of an approvable letter, an applicant may notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.110(b) states that, after receipt of an approvable letter, an ANDA applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (The burden hours for § 314.110(b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document.)

Section 314.120(a)(3) states that, after receipt of a not approvable letter, an applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (The burden hours for § 314.120(a)(3) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document.)

Section 314.120(a)(5) states that, after receipt of a not approvable letter, an applicant may notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.122(a) requires that an ANDA or a suitability petition that relies on a listed drug that has been voluntarily withdrawn from sale must be accompanied by a petition seeking a determination whether the drug was withdrawn for safety or effectiveness reasons. (The burden hours for § 314.122(a) are already approved by OMB under OMB control number 0910–0183 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.122(d) sets forth requirements for relisting petitions for unlisted discontinued products. (The burden hours for § 314.122(d) are already approved by OMB under OMB control number 0910–0183 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.126(c) sets forth requirements for a petition to waive criteria for adequate and well-controlled studies. (The burden hours for § 314.126(c) are already approved by OMB under 0910–0183 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.151(a) and (b) set forth requirements for the withdrawal of approval of an ANDA and the applicant's opportunity for a hearing and submission of comments. (The burden hours for § 314.151(a) and (b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document.)

Section 314.151(c) sets forth the requirements for withdrawal of approval of an ANDA and the applicant's opportunity to submit written objections and participate in a limited oral hearing. (The burden hours for § 314.151(c) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document.)

Section 314.152(b) sets forth the requirements for suspension of an ANDA when the listed drug is voluntarily withdrawn for safety and effectiveness reasons, and the applicant's opportunity to present comments and participate in a limited oral hearing. (The burden hours for § 314.152(b) is included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in table 1 of this document.)

Section 314.161(b) and (e) sets forth the requirements for submitting a petition to determine whether a listed drug was voluntarily withdrawn from sale for safety or effectiveness reasons. (The burden hours for § 314.161(b) and (e) are already approved by OMB under OMB control number 0910–0183 and are not included in the hour burden estimates in table 1 of this document.)

Section 314.200(c), (d), and (e) requires that applicants or others subject to a notice of opportunity for a hearing who wish to participate in a hearing file a written notice of participation and request for a hearing as well as the studies, data, and so forth, relied on. Other interested persons may also submit comments on the notice. This section also sets forth the content and format requirements for the applicants' submission in response to notice of

opportunity for hearing. (The burden hours for § 314.200(c), (d), and (e) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document.)

Section 314.200(f) states that participants in a hearing may make a motion to the presiding officer for the inclusion of certain issues in the hearing. (The burden hours for § 314.200(f) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document.)

Section 314.200(g) states that a person who responds to a proposed order from FDA denying a request for a hearing provide sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing. (The burden hours for § 314.200(g) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in table 1 of this document.)

Section 314.420 states that an applicant may submit to FDA a drug master file in support of an application, in accordance with certain content and format requirements.

Section 314.430 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that extraordinary circumstances exist. (The burden hours for § 314.430 is included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in table 1 of this document.)

Section 314.530(c) and (e) states that, if FDA withdraws approval of a drug approved under the accelerated approval procedures, the applicant has the opportunity to request a hearing and submit data and information. (The burden hours for § 314.530(c) and (e) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document.)

Section 314.530(f) requires that an applicant first submit a petition for stay of action before requesting an order from a court for a stay of action pending review. (The burden hours for § 314.530(f) are already approved by OMB under 0910–0194 and are not included in the hour burden estimates in table 1 of this document.)

In the **Federal Register** of October 8, 2004 (69 FR 60402), FDA announced an opportunity for public comment on these information collection estimates. No comments were submitted that pertained to the information collection estimates in the October 8, 2004, document.

Respondents to this collection of information are all persons who submit an application or abbreviated application or an amendment or supplement to FDA under part 314 to obtain approval of a new drug, and any person who owns an approved application or abbreviated application.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section; [FDA Form Number]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours Per Response	Total Hours
314.50 (a), (b), (c), (d), (e), (f), (h), and (k)	72	1.44	104	1,642	170,768
314.50(i) and 314.94(a)(12)	194	2.34	454	2	908
314.50(j)	70	3.71	260	2	520
314.52 and 314.95	24	2.25	54	16	864
314.54	16	1	16	300	4,800
314.60	275	19.06	5,242	80	419,320
314.65	10	1	10	2	20
314.70 and 314.71	234	10.99	2,572	150	385,800
314.72	61	4.52	276	2	552
314.81(b)(1) [3331]	115	3.88	447	8	3,576
314.81(b)(2) [2252]	612	12.47	7,632	40	305,280
314.81(b)(3)(i) [2253]	332	44.09	14,638	2	29,276
314.94(a) and (d)	100	4.59	459	480	220,320
314.96	275	23.63	6,500	80	520,000
314.97	200	16.75	3,350	80	268,000
314.99(a)	44	2.02	89	2	178
314.101(a)	2	1	2	.50	1

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section; [FDA Form Number]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours Per Response	Total Hours
314.107(c)(4), 314.107(e)(2)(iv), and 314.107(f)	3	2	6	1	6
314.110(a)(5)	41	1.26	52	.50	26
314.120(a)(5)	12	1.16	14	.50	7
314.420	403	1.72	694	61	42,334
Total					2,372,556

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1814 Filed 1–27–05; 12:53 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0514]

Draft Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Substances; Chemistry, Manufacturing, and Controls Information; 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 ''ANDAs: Impurities in Drug Substances; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on what chemistry, manufacturing, and controls information to include regarding the reporting, identification, and qualification of impurities in drug substances produced by chemical synthesis when submitting documentation for an abbreviated new drug application (ANDA), drug master file (DMF), or a supplement to support changes in drug substance synthesis or process.

DATES: Submit written or electronic comments on the draft guidance May 2, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Scott Furness, Center for Drug Evaluation and Research (HFD–640), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5849.

SUPPLEMENTARY INFORMATION:

I. Background

On December 3, 1999, FDA published in the **Federal Register** (64 FR 67917) the guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' The guidance provided recommendations for including information in ANDAs and supporting DMFs on the content and qualification of impurities in drug substances produced by chemical syntheses.

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs: Impurities in Drug Substances,'' which revises the December 3, 1999, guidance. The guidance is being revised to update information on listing of impurities, setting acceptance criteria, and qualifying impurities in conformance with the revision of the guidance for industry entitled ''Q3A Impurities in New Drug Substances'' (Q3A(R), published in February 2003). The guidance is also being revised to remove sections of the guidance containing recommendations that are no longer needed because they are addressed in the more recent Q3A(R).

This draft guidance contains information collection provisions 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 collection of information in this draft guidance was approved under OMB Control Nos. 0910–0001 and 0910–0032.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on these topics. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 24, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1752 Filed 1–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Supplemental Compliance Program Guidance for Hospitals

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the Supplemental Compliance Program Guidance (CPG) for Hospitals developed by the Office of Inspector General (OIG). Through this notice, the OIG is supplementing its prior compliance program guidance for hospitals issued in 1998. The supplemental CPG contains new compliance recommendations and an expanded discussion of risk areas, taking into account recent changes to hospital payment systems and regulations, evolving industry practices, current enforcement priorities, and lessons learned in the area of corporate compliance. The supplemental CPG provides voluntary guidelines to assist hospitals and hospital systems in identifying significant risk areas and in evaluating and, as necessary, refining ongoing compliance efforts.

FOR FURTHER INFORMATION CONTACT: Darlene M. Hampton, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Background

Several years ago, the OIG embarked on a major initiative to engage the private health care community in preventing the submission of erroneous claims and in combating fraud and abuse in the Federal health care programs through voluntary compliance efforts. In the last several years, the OIG has developed a series of compliance program guidances (CPGs) directed at the following segments of the health care industry: hospitals; clinical laboratories; home health agencies; third-party billing companies; the durable medical equipment, prosthetics, orthotics, and supply industry; hospices; Medicare+Choice organizations; nursing facilities; physicians; ambulance suppliers; and pharmaceutical manufacturers. CPGs are intended to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. The suggestions made in these CPGs are not mandatory, and the CPGs should not be viewed as exhaustive discussions of beneficial compliance practices or relevant risk areas. Copies of these CPGs can be found on the OIG Web page at *http://oig.hhs.gov.*

Supplementing the Compliance Program Guidance for Hospitals

The OIG originally published a CPG for the hospital industry on February 23, 1998. (*See* 63 FR 8987 (February 23, 1998), available on our Web page at *http://oig.hhs.gov/authorities/docs/cpghosp.pdf.*) Since that time, there have been significant changes in the way hospitals deliver, and are reimbursed for, health care services. In response to these developments, on June 18, 2002, the OIG published a notice in the **Federal Register,** soliciting public suggestions for revising the hospital CPG. (*See* 67 FR 41433 (June 18, 2002), available on our Web page at *http://oig.hhs.gov/authorities/docs/cpghospitalsolicitationnotice.pdf.*) After consideration of the public comments and the issues raised, the OIG published a draft supplemental compliance program guidance for hospitals in the **Federal Register** on June 8, 2004, to ensure that all parties had a reasonable and meaningful opportunity to provide input into the final product. (*See* 69 FR 32012 (June 8, 2004), available on our Web page at *http://oig.hhs.gov/authorities/docs/04/060804hospitaldraftsuppCPGFR.pdf.*) The OIG received comments from a variety of parties with interests in the hospital industry and diverse points of view. These comments were carefully considered during the development of this final supplemental CPG. While some commenters preferred a replacement CPG, for efficiency and to create a concise product of particular use to hospitals with existing compliance programs, we have decided to supplement, rather than replace, the 1998 guidance.

Many public commenters sought guidance on the application of specific Medicare rules and regulations related to payment and coverage, an area beyond the scope of this OIG guidance. Hospitals with questions about the interpretation or application of payment and coverage rules or regulations should contact their Fiscal Intermediaries (FIs) or the Centers for Medicare & Medicaid Services, as appropriate.

Supplemental Compliance Program Guidance for Hospitals

I. Introduction

Continuing its efforts to promote voluntary compliance programs for the health care industry, the Office of Inspector General (OIG) of the Department of Health and Human Services (the Department) publishes this Supplemental Compliance Program Guidance (CPG) for Hospitals.[1] This document supplements, rather than replaces, the OIG's 1998 CPG for the hospital industry (63 FR 8987; February 23, 1998), which addressed the fundamentals of establishing an effective compliance program.[2] Neither this supplemental CPG, nor the original 1998 CPG, is a model compliance program. Rather, collectively the two documents offer a set of guidelines that hospitals should consider when developing and implementing a new compliance program or evaluating an existing one.

We are mindful that many hospitals have already devoted substantial time and resources to compliance efforts. We believe that those efforts demonstrate the industry's good faith commitment to ensuring and promoting integrity. For those hospitals with existing compliance programs, this document may serve as a benchmark or comparison against which to measure ongoing efforts and as a roadmap for updating or refining their compliance plans.

In crafting this supplemental CPG, we considered, among other things, the public comments received in response to the solicitation notice published in the **Federal Register** [3] and the draft supplemental CPG,[4] as well as relevant OIG and Centers for Medicare & Medicaid Services (CMS) statutory and regulatory authorities (including the Federal anti-kickback statute, together with the safe harbor regulations and

[1] For purposes of convenience in this guidance, we use the term ''hospitals'' to refer to individual hospitals, multi-hospital systems, health systems that own or operate hospitals, academic medical centers, and any other organization that owns or operates one or more hospitals. Where applicable, the term ''hospitals'' is also intended to include, without limitation, hospital owners, officers, managers, staff, agents, and sub-providers. This guidance primarily focuses on hospitals reimbursed under the inpatient and outpatient prospective payment systems. While other hospitals should find this CPG useful, we recognize that they may be subject to different laws, rules, and regulations and, accordingly, may have different or additional risk areas and may need to adopt different compliance strategies. We encourage all hospitals to establish and maintain ongoing compliance programs.

[2] The 1998 OIG Compliance Program Guidance for Hospitals is available on our Web page at *http://oig.hhs.gov/authorities/docs/cpghosp.pdf.*

[3] *See* 67 FR 41433 (June 18, 2002), ''Solicitation of Information and Recommendations for Revising a Compliance Program Guidance for the Hospital Industry,'' available on our Web page at *http://oig.hhs.gov/authorities/docs/cpghospitalsolicitationnotice.pdf.*

[4] *See* 69 FR 32012 (June 8, 2004), ''OIG Draft Supplemental Compliance Program Guidance for Hospitals,'' available on our Web page at *http://oig.hhs.gov/authorities/docs/04/060804hospitaldraftsuppCPGFR.pdf.*

preambles,[5] and CMS transmittals and program memoranda); other OIG guidance (such as OIG advisory opinions, special fraud alerts, bulletins, and other guidance); experience gained from investigations conducted by the OIG's Office of Investigations, the Department of Justice (DoJ), and the State Medicaid Fraud Units; and relevant reports issued by the OIG's Office of Audit Services and Office of Evaluation and Inspections.[6] We also consulted generally with CMS, the Department's Office for Civil Rights, and DoJ.

A. Benefits of a Compliance Program

A successful compliance program addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing health care providers' operations; improving the quality of health care services; and reducing the overall cost of health care services. Attaining these goals benefits the hospital industry, the government, and patients alike. Compliance programs help hospitals fulfill their legal duty to refrain from submitting false or inaccurate claims or cost information to the Federal health care programs[7] or engaging in other illegal practices. A hospital may gain important additional benefits by voluntarily implementing a compliance program, including:

- Demonstrating the hospital's commitment to honest and responsible corporate conduct;
- Increasing the likelihood of preventing, identifying, and correcting unlawful and unethical behavior at an early stage;
- Encouraging employees to report potential problems to allow for appropriate internal inquiry and corrective action; and
- Through early detection and reporting, minimizing any financial loss to government and taxpayers, as well as any corresponding financial loss to the hospital.

The OIG recognizes that implementation of a compliance program may not entirely eliminate improper or unethical conduct from the operations of health care providers. However, an effective compliance program demonstrates a hospital's good faith effort to comply with applicable statutes, regulations, and other Federal health care program requirements, and may significantly reduce the risk of unlawful conduct and corresponding sanctions.

B. Application of Compliance Program Guidance

Given the diversity of the hospital industry, there is no single ''best'' hospital compliance program. The OIG recognizes the complexities of the hospital industry and the differences among hospitals and hospital systems. Some hospital entities are small and may have limited resources to devote to compliance measures; others are affiliated with well-established, large, multi-facility organizations with a widely dispersed work force and significant resources to devote to compliance.

Accordingly, this supplemental CPG is not intended to be one-size-fits-all guidance. Rather, the OIG strongly encourages hospitals to identify and focus their compliance efforts on those areas of potential concern or risk that are most relevant to their individual organizations. Compliance measures adopted by a hospital to address identified risk areas should be tailored to fit the unique environment of the organization (including its structure, operations, resources, and prior enforcement experience). In short, the OIG recommends that each hospital adapt the objectives and principles underlying this guidance to its own particular circumstances.

In section II below, titled ''Fraud and Abuse Risk Areas,'' we present several fraud and abuse risk areas that are particularly relevant to the hospital industry. Each hospital should carefully examine these risk areas and identify those that potentially impact the hospital. Next, in section III, ''Hospital Compliance Program Effectiveness,'' we offer recommendations for assessing and improving an existing compliance program to better address identified risk areas. Finally, in section IV, ''Self-Reporting,'' we set forth the actions hospitals should take if they discover credible evidence of misconduct.

II. Fraud and Abuse Risk Areas

This section is intended to help hospitals identify areas of their operations that present a potential risk of liability under several key Federal fraud and abuse statutes and regulations. This section focuses on areas that are currently of concern to the enforcement community and is not intended to address all potential risk areas for hospitals. Importantly, the identification of a particular practice or activity in this section is not intended to imply that the practice or activity is necessarily illegal in all circumstances or that it may not have a valid or lawful purpose underlying it.

This section addresses the following areas of significant concern for hospitals: (A) Submission of accurate claims and information; (B) the referral statutes; (C) payments to reduce or limit services; (D) the Emergency Medical Treatment and Labor Act (EMTALA); (E) substandard care; (F) relationships with Federal health care beneficiaries; (G) HIPAA Privacy and Security Rules; and (H) billing Medicare or Medicaid substantially in excess of usual charges. In addition, a final section (I) addresses several areas of general interest that, while not necessarily matters of significant risk, have been of continuing interest to the hospital community. This guidance does not create any new law or legal obligations, and the discussions in this guidance are not intended to present detailed or comprehensive summaries of lawful and unlawful activity. Nor is this guidance intended as a substitute for consultation with CMS or a hospital's Fiscal Intermediary (FI) with respect to the application and interpretation of Medicare payment and coverage provisions, which are subject to change. Rather, this guidance should be used as a starting point for a hospital's legal review of its particular practices and for development or refinement of policies and procedures to reduce or eliminate potential risk.

A. Submission of Accurate Claims and Information

Perhaps the single biggest risk area for hospitals is the preparation and submission of claims or other requests for payment from the Federal health care programs. It is axiomatic that all claims and requests for reimbursement from the Federal health care programs—and all documentation supporting such claims or requests—must be complete and accurate and must reflect reasonable and necessary services ordered by an appropriately licensed medical professional who is a participating provider in the health care program from which the individual or entity is seeking reimbursement. Hospitals must disclose and return any overpayments that result from mistaken

[5] *See* 42 U.S.C. 1320a–7b(b). *See also* 42 CFR 1001.952. The safe harbor regulations and preambles are available on our Web page at *http://oig.hhs.gov/fraud/safeharborregulations.html#1.*

[6] The OIG's materials are available on our Web page at *http://oig.hhs.gov.*

[7] The term ''Federal health care programs,'' as defined in 42 U.S.C. 1320a–7b(f), includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the Federal Employees Health Benefit Plan described at 5 U.S.C. 8901–8914) or any State health plan (*e.g.,* Medicaid or a program receiving funds from block grants for social services or child health services). In this document, the term ''Federal health care program requirements'' refers to the statutes, regulations, and other rules governing Medicare, Medicaid, and all other Federal health care programs.

or erroneous claims.[8] Moreover, the knowing submission of a false, fraudulent, or misleading statement or claim is actionable. A hospital may be liable under the False Claims Act[9] or other statutes imposing sanctions for the submission of false claims or statements, including liability for civil money penalties (CMPs) or exclusion.[10] Underlying assumptions used in connection with claims submission should be reasoned, consistent, and appropriately documented, and hospitals should retain all relevant records reflecting their efforts to comply with Federal health care program requirements.

Common and longstanding risks associated with claims preparation and submission include inaccurate or incorrect coding, upcoding, unbundling of services, billing for medically unnecessary services or other services not covered by the relevant health care program, billing for services not provided, duplicate billing, insufficient documentation, and false or fraudulent cost reports. While hospitals should continue to be vigilant with respect to these important risk areas, we believe these risk areas are relatively well-understood in the industry and, therefore, they are not generally addressed in this section.[11] Rather, the following discussion highlights evolving risks or risks that appear to the OIG to be under-appreciated by the industry. The risks are grouped under the following topics: Outpatient procedure coding; admissions and discharges; supplemental payment considerations; and use of information technology. By necessity, this discussion is illustrative, not exhaustive, of risks associated with the submission of claims or other information. In all cases, hospitals should consult the applicable laws, rules, and regulations.

1. Outpatient Procedure Coding

The implementation of Medicare's Hospital Outpatient Prospective Payment System (OPPS)[12] increased the importance of accurate procedure coding for hospital outpatient services. Previously, hospital coding concerns mainly consisted of ensuring accurate ICD–9–CM diagnosis and procedure coding for reimbursement under the inpatient prospective payment system (PPS). Hospitals reported procedure codes for outpatient services, but were reimbursed for outpatient services based on their charges for services. With the OPPS, procedure codes effectively became the basis for Medicare reimbursement. Under the OPPS, each reported procedure code is assigned to a corresponding Ambulatory Payment Classification (APC) code. Hospitals are then reimbursed a predetermined amount for each APC, irrespective of the specific level of resources used to furnish the individual service. In implementing the OPPS, CMS developed new rules governing the use of procedure code modifiers for outpatient coding.[13] Because incorrect procedure coding may lead to overpayments and subject a hospital to liability for the submission of false claims, hospitals need to pay close attention to coder training and qualifications.

Hospitals should also review their outpatient documentation practices to ensure that claims are based on complete medical records and that the medical records support the levels of service claimed. Under the OPPS, hospitals must generally include on a single claim all services provided to the same patient on the same day. Coding from incomplete medical records may create problems in complying with this claim submission requirement. Moreover, submitting claims for services that are not supported by the medical record may also result in the submission of improper claims.

In addition to the coding risk areas noted above and in the 1998 hospital CPG, other specific risk areas associated with incorrect outpatient procedure coding include the following:

• *Billing on an outpatient basis for ''inpatient-only'' procedures*—CMS has identified procedures for which reimbursement is typically allowed only if the service is performed in an inpatient setting.[14]

• *Submitting claims for medically unnecessary services by failing to follow the FI's local policies*—Each FI publishes local policies, including local medical review polices (LMRPs) and local coverage determinations (LCDs), that identify certain procedures that are only reimbursable when specific conditions are present.[15] In addition to relying on a physician's sound clinical judgment with respect to the appropriateness of a proposed course of treatment, hospitals should regularly review and become familiar with their individual FI's LMRPs and LCDs. LMRPs and LCDs should be incorporated into a hospital's regular coding and billing operations.[16]

• *Submitting duplicate claims or otherwise not following the National Correct Coding Initiative guidelines*—CMS developed the National Correct Coding Initiative (NCCI) to promote correct coding methodologies. The NCCI identifies certain codes that should not be used together because they are either mutually exclusive or one is a component of another. If a hospital uses code pairs that are listed in the NCCI and those codes are not detected by the editing routines in the hospital's billing system, the hospital may submit duplicate or unbundled claims. Intentional manipulation of code assignments to maximize payments and avoid NCCI edits constitutes fraud. Unintentional misapplication of NCCI coding and billing guidelines may also give rise to overpayments or civil liability for hospitals that have developed a pattern of inappropriate billing. To minimize risk, hospitals

[8] *See* 42 U.S.C. 1320a–7b(a)(3).

[9] The False Claims Act (31 U.S.C. 3729–33), among other things, prohibits knowingly presenting or causing to be presented to the Federal government a false or fraudulent claim for payment or approval, knowingly making or using or causing to be made or used a false record or statement to have a false or fraudulent claim paid or approved by the government, and knowingly making or using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government. The False Claims Act defines ''knowing'' and ''knowingly'' to mean that ''a person, with respect to the information—(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.'' 31 U.S.C. 3729(b).

[10] In some circumstances, inaccurate or incomplete reporting may lead to liability under the Federal anti-kickback statute. In addition, hospitals should be mindful that many States have fraud and abuse statutes—including false claims, anti-kickback, and other statutes—that are not addressed in this guidance.

[11] To review the risk areas discussed in the original hospital CPG, *see* 63 FR 8987, 8990 (February 23, 1998), available on our Web page at *http://oig.hhs.gov/authorities/docs/cpghosp.pdf.*

[12] Congress enacted the OPPS in section 4523 of the Balanced Budget Act of 1997. The OPPS became effective on August 1, 2001. CMS promulgated regulations implementing the OPPS at 42 CFR part 419. For more information regarding the OPPS, *see http://www.cms.gov/providers/hopps/.*

[13] The list of current modifiers is listed in the Current Procedural Terminology (CPT) coding manual. However, hospitals should pay particular attention to CMS transmittals and program memoranda that may introduce new or altered application of modifiers for claims submission and reimbursement purposes. *See* chapter 4, section 20.6 of the Medicare Claims Processing Manual at *http://www.cms.gov/manuals/104_claims/clm104c04.pdf.*

[14] The list of ''inpatient-only'' procedures appears in the annual update to the OPPS rule. For the 2004 final rule, the ''inpatient-only'' list is found in Addendum E. *See http://www.cms.gov/regulations/hopps/2004f.*

[15] Effective December 7, 2003, FI's began issuing LCDs instead of LMRPs, and FI's will convert all existing LMRPs into LCDs by December 31, 2005.

[16] A hospital may contact its FI to request a copy of the pertinent LMRPs and LCDs, or visit CMS's Web page at *http://www.cms.gov/mcd* to search existing local and national policies.

should ensure that their coding software includes up-to-date NCCI edit files.[17]

• *Submitting incorrect claims for ancillary services because of outdated Charge Description Masters*—Charge Description Masters (CDMs) list all of a hospital's charges for items and services and include the underlying procedure codes necessary to bill for those items and services. Outdated CDMs create significant compliance risk for hospitals. Because the Healthcare Common Procedure Coding System (HCPCS) codes and APCs are updated regularly, hospitals should pay particular attention to the task of updating the CDM to ensure the assignment of correct codes to outpatient claims. This should include timely updates, proper use of modifiers, and correct associations between procedure codes and revenue codes.[18]

• *Circumventing the multiple procedure discounting rules*—A surgical procedure performed in connection with another surgical procedure may be discounted. However, certain surgical procedures are designated as non-discounted, even when performed with another surgical procedure. Hospitals should ensure that the procedure codes selected represent the actual services provided, irrespective of the discounting status. They should also review the annual OPPS rule update to understand more fully CMS's multiple procedure discounting rule.[19]

• *Improper evaluation and management code selection*—Hospitals should use proper codes to describe the evaluation and management (E/M) services they provide. A hospital's E/M coding guidelines should ensure that services are medically necessary and sufficiently documented and that the codes accurately reflect the intensity of hospital resources required to deliver the services.

• *Improperly billing for observation services*—In certain circumstances, Medicare provides a separate APC payment for observation services for patients with diagnoses of chest pain, asthma, or congestive heart failure. Claims for these observation services must correctly reflect the diagnosis and meet certain other requirements. Seeking a separate payment for observation services in situations that do not satisfy the requirements is inappropriate and may result in hospital liability. Hospitals should become familiar with CMS's detailed policies for the submission of claims for observation services.[20]

2. Admissions and Discharges

Often, the status of patients at the time of admission or discharge significantly influences the amount and method of reimbursement hospitals receive. Therefore, hospitals have a duty to ensure that admission and discharge policies are updated and reflect current CMS rules. Risk areas with respect to the admission and discharge processes include the following:

• *Failure to follow the ''same-day rule''*—The OPPS rules require hospitals to include on the same claim all OPPS services provided at the same hospital, to the same patient, on the same day, unless certain conditions are met. Hospitals should review internal billing systems and procedures to ensure that they are not submitting multiple claims for OPPS services delivered to the same patient on the same day.[21]

• *Abuse of partial hospitalization payments*—Under the OPPS, Medicare provides a *per diem* payment for specific hospital services rendered to behavioral and mental health patients on a partial hospitalization basis. Examples of improper billing under the partial hospitalization program include, without limitation: reducing the range of services offered; withholding services that are medically appropriate; billing for services not covered; and billing for services without a certificate of medical necessity.[22]

• *Same-day discharges and readmissions*—Same-day discharges and readmissions may indicate premature discharges, medically unnecessary readmissions, or incorrect discharge coding. Hospitals should have procedures in place to review discharges and admissions carefully to ensure that they reflect prudent clinical decision-making and are properly coded.[23]

• *Violation of Medicare's post-acute care transfer policy*—The post-acute care transfer policy provides that, for certain designated Diagnosis Related Groups (DRGs), a hospital will receive a per diem transfer payment, rather than the full DRG payment, if the patient is discharged to certain post-acute care settings.[24] CMS may periodically revise the list of designated DRGs that are subject to its post-acute care transfer policy.[25] To avoid improperly billing for discharges, hospitals should pay particular attention to CMS's post-acute care transfer policy and keep an accurate list of all designated DRGs subject to that policy.

• *Improper churning of patients by long-term care hospitals co-located in acute care hospitals*—Long term care hospitals that are co-located within acute care hospitals may qualify for PPS-exempt status if certain regulatory requirements are satisfied.[26] Hospitals should not engage in the practice of churning, or inappropriately transferring, patients between the host hospital and the hospital-within-a-hospital.

3. Supplemental Payment Considerations

Under the Medicare program, in certain limited situations, hospitals may claim payments in addition to, or in some cases in lieu of, the normal reimbursement available to hospitals under the regular payment systems. Eligibility for these payments depends on compliance with specific criteria. Hospitals that claim supplemental payments improperly are liable for fines and penalties under Federal law. Examples of specific risks that hospitals should address include the following:

• *Improper reporting of the costs of ''pass-through'' items*—''Pass-through'' items are certain items of new technology and drugs for which Medicare will reimburse the hospital

[17] More information regarding the NCCI can be obtained from CMS's Web page at *http://www.cms.gov/medlearn/ncci.asp.*

[18] For information relating to HCPCS code updates, *see http://www.cms.gov/medicare/hcpcs/.* For information relating to annual APC updates, *see http://www.cms.gov/providers/hopps/.*

[19] *See http://www.cms.gov/medlearn/refopps.asp.*

[20] *See* CMS Program Transmittal A–02–026, available on CMS's Web page at *http://www.ems.gov/manuals/pm_trans/A02026.pdf.*

[21] *See, e.g.,* chapter 1, section 50.2 of the Medicare Claims Processing Manual, available on CMS's Web page at *http://www.cms.gov/manuals/104_claims/clm104c01.pdf.*

[22] *See* chapter 4, section 260 of the Medicare Claims Processing Manual, available on CMS's Web page at *http://www.cms.gov/manuals/104_claims/clm104c04.pdf.*

[23] *See, e.g.,* OIG Audit Report A–03–01–00011, ''Review of Medicare Same-Day, Same-Provider Acute Care Readmissions in Pennsylvania During Calendar year 1998,'' August 2002, available on our Web page at *http://oig.hhs.gov/oas/reports/region 3/30100011.pdf.*

[24] *See* 42 CFR 412.4(c). *See, e.g.,* OIG Audit Report A–04–00–01220 ''Implementation of Medicare's Postacute Care Transfer Policy,'' October 2001, available on our Web page at *http://oig.hhs.gov/oas/reports/region4/40001220.pdf.*

[25] The initial 10 designated DRGs were selected by the Secretary, pursuant to section 1886(d)(5)(J) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(J)). With the 2004 fiscal year PPS rule, CMS revised the list of DRGs paid under CMS's post-acute care transfer policy, bringing the total number of designated DRGs to 29. *See* 68 FR 45346 (August 1, 2003). Then, with the 2005 fiscal year PPS rule, CMS revised the list again, bringing the current total number of designated DRGs to 30. *See* 69 FR 48916 (August 11, 2004). *See also* chapter 3, section 402.4 of the Medicare Claims Processing Manual, available on CMS's Web page at *http://www.cms.gov/manuals/104_claims/clm104c03.pdf.*

[26] *See* 42 CFR 412.22(e).

based on costs during a limited transitional period.[27]

• *Abuse of DRG outlier payments*—Recent investigations revealed substantial abuse of outlier payments by hospitals with Medicare patients. Hospital management, compliance staff, and counsel should familiarize themselves with CMS's new outlier rules and requirements intended to curb abuses.[28]

• *Improper claims for incorrectly designated ''provider-based'' entities*—Certain hospital-affiliated entities and clinics can be designated as ''provider-based,'' which allows for a higher level of reimbursement for certain services.[29] Hospitals should take steps to ensure that facilities or organizations are only designated as provider-based if they satisfy the criteria set forth in the regulations.

• *Improper claims for clinical trials*—Since September 2000, Medicare has covered items and services furnished during certain clinical trials, as long as those items and services would typically be covered for Medicare beneficiaries, but for the fact that they are provided in an experimental or clinical trial setting. Hospitals that participate in clinical trials should review the requirements for submitting claims for patients participating in clinical trials.[30]

• *Improper claims for organ acquisition costs*—Hospitals that are approved transplantation centers may receive reimbursement on a reasonable cost basis to cover the costs of acquisition of certain organs.[31] Organ acquisition costs are only reimbursable if a hospital satisfies several requirements, such as having adequate cost information, supporting documentation, and supporting medical records.[32] Hospitals must also ensure that expenses not related to organ acquisition, such as transplant and post-transplant activities and costs from other cost centers, are not included in the hospital's organ acquisition costs.[33]

• *Improper claims for cardiac rehabilitation services*—Medicare covers reasonable and necessary cardiac rehabilitation services under the hospital ''incident-to'' benefit, which requires that the services of nonphysician personnel be furnished under a physician's direct supervision. In addition to satisfying the supervision requirement, hospitals must ensure that cardiac rehabilitation services are reasonable and necessary.[34]

• *Failure to follow Medicare rules regarding payment for costs related to educational activities*[35]—Hospitals should pay particular attention to these rules when implementing dental or other education programs, particularly those not historically operated at the hospital.

4. Use of Information Technology

The implementation of the OPPS increased the need for hospitals to pay particular attention to their computerized billing, coding, and information systems. Billing and coding under the OPPS is more data intensive than billing and coding under the inpatient PPS. When the OPPS began, many hospitals' existing systems were unable to accommodate the new requirements and required adjustments.

As the health care industry moves forward, hospitals will increasingly rely on information technology. For example, HIPAA Privacy and Security Rules (discussed below in section II.G), electronic claims submission,[36] electronic prescribing, networked information sharing among providers, and systems for the tracking and reduction of medical errors, among others, will require hospitals to depend more on information technologies. Information technology presents new opportunities to advance health care efficiency, but also new challenges to ensuring the accuracy of claims and the information used to generate claims. It may be difficult for purchasers of computer systems and software to know exactly how the system operates and generates information. Prudent hospitals will take steps to ensure that they thoroughly assess all new computer systems and software that impact coding, billing, or the generation or transmission of information related to the Federal health care programs or their beneficiaries.

B. The Referral Statutes: The Physician Self-Referral Law (the ''Stark'' Law) and the Federal Anti-Kickback Statute

1. The Physician Self-Referral Law

From a hospital compliance perspective, the physician self-referral law (section 1877 of the Social Security Act (Act), commonly known as the ''Stark'' law) should be viewed as a threshold statute. The statute prohibits hospitals from submitting—and Medicare from paying—any claim for a ''designated health service'' (DHS) if the referral of the DHS comes from a physician with whom the hospital has a prohibited financial relationship.[37] This is true even if the prohibited financial relationship is the result of inadvertence or error. In addition, hospitals and physicians that *knowingly* violate the statute may be subject to CMPs and exclusion from the Federal health care programs. Furthermore, under certain circumstances, a knowing violation of the Stark law may also give rise to liability under the False Claims Act. Because all inpatient and outpatient hospital services furnished to Medicare or Medicaid patients

[27] For more information regarding CMS's APC ''pass-through'' payments, *See http://www.cms.gov/providers/hopps/apc.asp.*

[28] *See* 42 CFR 412.84; 68 FR 34493 (June 9, 2003).

[29] The criteria for determining whether a facility or organization is provider-based can be found at 42 CFR 413.65. In April 2003, CMS published Transmittal A–03–030, outlining changes to the criteria for provider-based designation. *See http://www.cms.gov/manuals/pm_trans/A03030.pdf.*

[30] To view Medicare's National Coverage Decision regarding clinical trials, *see http://www.cms.gov/coverage/8d2.asp.* Specific requirements for submitting claims for reimbursement for clinical trials can be accessed on CMS's Web page at *http://www.cms.gov/coverage/8d4.asp.*

[31] *See* 42 CFR 412.2(e)(4), 42 CFR 412.113(d), and 42 CFR 413.203. *See generally* 42 CFR part 413 (setting forth the principles of reasonable cost reimbursement).

[32] *See* Medicare's Provider Reimbursement Manual (PRM), Part I, section 2304 and Part II, section 3610, available on CMS's Web page at *http://www.cms.gov/manuals/cmsfoc.asp.*

[33] *See* 42 CFR 412.100. *See also,* chapter 3, section 90 of the Medicare Claims Processing Manual, available on CMS's Web page at *http://www.cms.gov/manuals/104_claims/clm104c03.pdf.See, e.g.,* OIG Audit Report A–04–02–02017, ''Audit of Medicare Costs for Organ Acquisitions at Tampa General Hospital,'' April 2003, available on our Web page at *http://oig.hhs.gov/oas/reports/region4/40202017.pdf.*

[34] *See* section 35–25 of the Medicare Coverage Issues Manual. *See, e.g.,* OIG Audit Report A–01–03–00516, ''Review of Outpatient Cardiac Rehabilitation Services at the Cooley Dickinson Hospital,'' December 2003, available on our Web page at *http://oig.hhs.gov/oas/reports/region 1/10300516.pdf.*

[35] Payments for direct graduage medical education (GME) and indirect graduate medical education (IME) costs are, in part, based upon the number of full-time equivalent (FTE) residents at each hospital and the proportion of time residents spend in training. Hospitals that inappropriately calculate the number of FTE residents risk receiving inappropriate medical education payments. Hospitals should have in place procedures regarding: (i) Resident rotation monitoring; (ii) resident credentialing; (iii) written agreements with non-hospital providers; and (iv) the approval process for research activities. For more information regarding medical education reimbursement, *see* 42 CFR 413.75 *et. seq.* (GME requirements) and 42 CFR 412.105 (IME requirements). *See, e.g.,* OIG Audit Report A–01–01–00547 ''Review of Graduate Medical Education Costs Claimed by the Hartford Hospital for Fiscal Year Ending September 30, 1999,'' October 2003, available on our Web page at *http://oig.hhs.gov/oas/reports/region 1/10100547.pdf.*

[36] For more information regarding Medicare's Electronic Data Interchange programs, *see http://www.cms.gov/providers/edi/.*

[37] The statute also prohibits physicians from referring DHS to entities, including hospitals, with which they have prohibited financial relationships. However, the billing prohibition and nonpayment sanction apply only to the DHS entity (*e.g.*, the hospital). *See* section 1877(a) of the Act. Section 1903(s) of the Act extends the statutory prohibition to Medicaid-covered services.

(including services furnished directly by a hospital or by others ''under arrangements'' with a hospital) are DHS under the statute,[38] hospitals must diligently review all financial relationships with referring physicians for compliance with the Stark law. Simply put, hospitals face significant financial exposure unless their financial relationships with referring physicians fit squarely in statutory or regulatory exceptions to the Stark law.

For purposes of analyzing a financial relationship under the Stark law, the following three-part inquiry is useful:

- Is there a *referral* from a *physician* for a *designated health service*? If not, then there is no Stark law issue (although other fraud and abuse authorities, such as the anti-kickback statute, may be implicated). If the answer is ''yes,'' the next inquiry is:
- Does the physician (or an immediate family member) have a *financial relationship* with the entity furnishing the DHS (*e.g.*, the hospital)? Again, if the answer is no, the Stark law is not implicated. However, if the answer is ''yes,'' the third inquiry is:
- Does the financial relationship fit in an *exception*? If not, the statute has been violated.

Detailed definitions of the highlighted terms are set forth in regulations at 42 CFR 411.351 through 411.361 (substantial additional explanatory material appears in the regulatory preambles to the final regulations: 66 FR 856 (January 4, 2001); 69 FR 16054 (March 26, 2004); and 69 FR 17933 (April 6, 2004)). Importantly, a financial relationship can be almost any kind of direct or indirect ownership or investment relationship (*e.g.*, stock ownership, a partnership interest, or secured debt) or direct or indirect compensation arrangement, whether in cash or in-kind (*e.g.*, a rental contract, personal services contract, salary, gift, or gratuity), between a referring physician (or immediate family member) and a hospital. Moreover, the financial relationship need not relate to the provision of DHS (*e.g.*, a joint venture between a hospital and a physician to operate a hospice would create an indirect compensation relationship between the hospital and the physician for Stark law purposes).

[38] The statute lists ten additional categories of DHS, including, among others, clinical laboratory services, radiology services, and durable medical equipment. See section 1877(h)(6) of the Act. Hospitals and health systems that own or operate free-standing DHS entities should be mindful of the ten additional DHS categories. CMS has clarified that lithotripsy services furnished to hospital inpatients are not DHS. See 69 FR 16054, 16106 (March 26, 2004).

The statutory and regulatory exceptions are the key to compliance with the Stark law. Any financial relationship between the hospital and a physician who refers to the hospital must fit in an exception. Exceptions exist in the statute and regulations for many common types of business arrangements. To fit in an exception, an arrangement must squarely meet all of the conditions set forth in the exception. Importantly, it is the actual relationship between the parties, and not merely the paperwork, that must fit in an exception. Unlike the anti-kickback safe harbors, which are voluntary, fitting in an exception is mandatory under the Stark law.

Compliance with a Stark law exception does not immunize an arrangement under the anti-kickback statute. Rather, the Stark law sets a minimum standard for arrangements between physicians and hospitals. Even if a hospital-physician relationship qualifies for a Stark law exception, it should still be reviewed for compliance with the anti-kickback statute. The anti-kickback statute is discussed in greater detail in the next subsection.

Because of the significant exposure for hospitals under the Stark law, we recommend that hospitals implement systems to ensure that all conditions in the exceptions upon which they rely are fully satisfied. For example, many of the exceptions, such as the rental and personal services exceptions, require signed, written agreements with physicians. We are aware of numerous instances in which hospitals failed to maintain these signed written agreements, often inadvertently (*e.g.*, a holdover lease without a written lease amendment; a physician hired as an independent contractor for a short-term project without a signed agreement). To avoid a large overpayment, hospitals should ensure frequent and thorough review of their contracting and leasing processes. The final regulations contain a new limited exception for certain inadvertent, temporary instances of noncompliance with another exception. This exception may only be used on an occasional basis. Hospitals should be mindful that this exception is not a substitute for vigilant contracting and leasing oversight. In addition, hospitals should review the new reporting requirements at 42 CFR 411.361, which generally require hospitals to retain records that the hospitals know or should know about in the course of prudently conducting business. Hospitals should ensure that they have policies and procedures in place to address these reporting requirements.

In addition, because many exceptions to the Stark law require fair market value compensation for items or services actually needed and rendered, hospitals should have appropriate processes for making and documenting reasonable, consistent, and objective determinations of fair market value and for ensuring that needed items and services are furnished or rendered. Other areas that may require careful monitoring include, without limitation, the total value of nonmonetary compensation provided annually to each referring physician, the value of medical staff incidental benefits, and the provision of professional courtesy.[39] As discussed further in the anti-kickback section below, hospitals should exercise care when recruiting physicians. Importantly, while the final regulations contain a limited exception for certain joint recruiting by hospitals and existing group practices, the exception strictly forbids the use of income guarantees that shift group practice overhead or expenses to the hospital or any payment structure that otherwise transfers remuneration to the group practice.

Further information about the Stark law and applicable regulations can be found on CMS's Web page at *http://cms.gov/medlearn/refphys.asp.* Information regarding CMS's Stark advisory opinion process can be found at *http://cms.gov/physicians/aop/default.asp*.

2. The Federal Anti-Kickback Statute

Hospitals should also be aware of the Federal anti-kickback statute, section 1128B(b) of the Act, and the constraints it places on business arrangements related directly or indirectly to items or services reimbursable by any Federal health care program, including, but not limited to, Medicare and Medicaid. The anti-kickback statute prohibits in the health care industry some practices that are common in other business sectors, such as offering gifts to reward past or potential new referrals.

The anti-kickback statute is a criminal prohibition against payments (in any form, whether the payments are direct

[39] Hospitals affiliated with academic medical centers should be aware that the regulations contain a special exception for certain academic medical center arrangements. *See* 42 CFR 411.355(e). Specialty hospitals should be mindful of certain limitations on new physician-owned specialty hospitals contained in section 507 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. *See* CMS's One-Time Notification regarding the 18-month moratorium on physician investment in specialty hospitals, CMS Manual System Pub. 100–20 One-Time Notification, Transmittal 26 (March 19, 2004), available on CMS's Web page at *http://www.cms.gov/manuals/pm_trans/R62OTN.pdf*.

or indirect) made purposefully to induce or reward the referral or generation of Federal health care program business. The anti-kickback statute addresses not only the offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or in part by a Federal health care program. The statute extends equally to the solicitation or acceptance of remuneration for referrals or the generation of other business payable by a Federal health care program. Liability under the anti-kickback statute is determined separately for each party involved. In addition to criminal penalties, violators may be subject to CMPs and exclusion from the Federal health care programs. Hospitals should also be mindful that compliance with the anti-kickback statute is a condition of payment under Medicare and other Federal health care programs. *See, e.g.*, Medicare Federal Health Care Provider/Supplier Application, CMS Form 855A, Certification Statement at section 15, paragraph A.3, available on CMS's Web page at *http://www.cms.gov/providers/enrollment/forms/*. As such, liability may arise under the False Claims Act where the anti-kickback statute violation results in the submission of a claim for payment under a Federal health care program.

Although liability under the anti-kickback statute ultimately turns on a party's intent, it is possible to identify arrangements or practices that may present a significant potential for abuse. For purposes of analyzing an arrangement or practice under the anti-kickback statute, the following two inquiries are useful:

- Does the hospital have any remunerative relationship between itself (or its affiliates or representatives) and persons or entities in a position to generate Federal health care program business for the hospital (or its affiliates) directly or indirectly? Persons or entities in a position to generate Federal health care program business for a hospital include, for example, physicians and other health care professionals, ambulance companies, clinics, hospices, home health agencies, nursing facilities, and other hospitals.
- With respect to any remunerative relationship so identified, could *one* purpose of the remuneration be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program? Importantly, under the anti-kickback statute, neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (*i.e.*, inducing Federal health care program business).

Although any arrangement satisfying both tests implicates the anti-kickback statute and requires careful scrutiny by a hospital, the courts have identified several potentially aggravating considerations that can be useful in identifying arrangements at greatest risk of prosecution. In particular, hospitals should ask the following questions, among others, about any potentially problematic arrangements or practices they identify:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to increase costs to Federal health care programs, beneficiaries, or enrollees?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Hospitals that have identified potentially problematic arrangements or practices can take a number of steps to reduce or eliminate the risk of an anti-kickback violation. Detailed guidance relating to a number of specific practices is available from several sources. Most importantly, the anti-kickback statute and the corresponding regulations establish a number of ''safe harbors'' for common business arrangements. The following safe harbors are of most relevance to hospitals:

- Investment interests safe harbor (42 CFR 1001.952(a)),
- Space rental safe harbor (42 CFR 1001.952(b)),
- Equipment rental safe harbor (42 CFR 1001.952(c)),
- Personal services and management contracts safe harbor (42 CFR 1001.952(d)),
- Sale of practice safe harbor (42 CFR 1001.952(e)),
- Referral services safe harbor (42 CFR 1001.952(f)),
- Discount safe harbor (42 CFR 1001.952(h)),
- Employee safe harbor (42 CFR 1001.952(i)),
- Group purchasing organizations safe harbor (42 CFR 1001.952(j)),
- Waiver of beneficiary coinsurance and deductible amounts safe harbor (42 CFR 1001.952(k)),
- Practitioner recruitment safe harbor (42 CFR 1001.952(n)),
- Obstetrical malpractice insurance subsidies safe harbor (42 CFR 1001.952(o)),
- Cooperative hospital service organizations safe harbor (42 CFR 1001.952(q)),
- Ambulatory surgical centers safe harbor (42 CFR 1001.952(r)),
- Ambulance replenishing safe harbor (42 CFR 1001.952(v)), and
- Safe harbors for certain managed care and risk sharing arrangements (42 CFR 1001.952(m), (t), and (u)).[40]

Safe harbor protection requires strict compliance with all applicable conditions set out in the relevant safe harbor.[41] Although compliance with a safe harbor is *voluntary* and failure to comply with a safe harbor does *not* mean an arrangement is illegal per se, we recommend that hospitals structure arrangements to fit in a safe harbor whenever possible. Arrangements that do not fit in a safe harbor must be evaluated on a case-by-case basis.

Other available guidance includes special fraud alerts and advisory bulletins issued by the OIG identifying and discussing particular practices or issues of concern and OIG advisory opinions issued to specific parties about their particular business arrangements.[42] A hospital concerned about an existing or proposed arrangement may request a binding OIG advisory opinion regarding whether the arrangement violates the Federal anti-kickback statute or other OIG fraud and abuse authorities, using the procedures set out at 42 CFR part 1008. The safe harbor regulations (and accompanying **Federal Register** preambles), fraud alerts and bulletins, advisory opinions (and instructions for obtaining them, including a list of frequently asked questions), and other guidance are

[40] Importantly, the anti-kickback statute safe harbors are not the same as the Stark law exceptions described above at section II.B.1 of this guidance. An arrangement's compliance with the anti-kickback statute and the Stark law must be evaluated separately.

[41] Parties to an arrangement cannot obtain safe harbor protection by entering into a sham contract that complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but does not reflect the actual arrangement between the parties. In other words, in assessing compliance with a safe harbor, the OIG examines not only whether the written contract satisfies all of the safe harbor requirements, but also whether the actual arrangement satisfies the requirements.

[42] While informative for guidance purposes, an OIG advisory opinion is binding only with respect to the particular party or parties that requested the opinion. The analyses and conclusions set forth in OIG advisory opinions are very fact-specific. Accordingly, hospitals should be aware that different facts may lead to different results.

available on the OIG Web page at *http://oig.hhs.gov.*

The following discussion highlights several known areas of potential risk under the anti-kickback statute. The propriety of any particular arrangement can only be determined after a detailed examination of the attendant facts and circumstances. The identification of a given practice or activity as ''suspect'' or as an area of ''risk'' does not mean it is necessarily illegal or unlawful, or that it cannot be properly structured to fit in a safe harbor; nor does it mean that the practice or activity is not beneficial from a clinical, cost, or other perspective. Rather, the areas identified below are areas of activity that have a potential for abuse and that should receive close scrutiny from hospitals. The discussion highlights potential risks under the anti-kickback statute arising from hospitals' relationships in the following seven categories: (a) Joint ventures; (b) compensation arrangements with physicians; (c) relationships with other health care entities; (d) recruitment arrangements; (e) discounts; (f) medical staff credentialing; and (g) malpractice insurance subsidies. (In addition, the kickback risks associated with gainsharing arrangements are discussed below in section II.C of this guidance.)

Physicians are the primary referral source for hospitals, and, therefore, most of the discussion below focuses on hospitals' relationships with physicians. Notwithstanding, hospitals also receive referrals from other health care professionals, including physician assistants and nurse practitioners, and from other providers and suppliers (such as ambulance companies, clinics, hospices, home health agencies, nursing facilities, and other hospitals). Therefore, in addition to reviewing their relationships with physicians, hospitals should also review their relationships with nonphysician referral sources to ensure that the relationships do not violate the anti-kickback statute. The principles described in the following discussions can be used to assess the risk associated with relationships with both physician and nonphysician referral sources.

a. Joint Ventures

The OIG has a long-standing concern about joint venture arrangements between those in a position to refer or generate Federal health care program business and those providing items or services reimbursable by Federal health care programs.[43] In the context of joint ventures, our chief concern is that remuneration from a joint venture might be a disguised payment for past or future referrals to the venture or to one or more of its participants. Such remuneration may take a variety of forms, including dividends, profit distributions, or, with respect to contractual joint ventures, the economic benefit received under the terms of the operative contracts.

When scrutinizing joint ventures under the anti-kickback statute, hospitals should examine the following factors, among others:

• *The manner in which joint venture participants are selected and retained.* If participants are selected or retained in a manner that takes into account, directly or indirectly, the value or volume of referrals, the joint venture is suspect. The existence of one or more of the following indicators suggests that there might be an improper nexus between the selection or retention of participants and the value or volume of their referrals:

—A substantial number of participants are in a position to make or influence referrals to the venture, other participants, or both;
—Participants that are expected to make a large number of referrals are offered a greater or more favorable investment or business opportunity in the joint venture than those anticipated to make fewer referrals;
—Participants are actively encouraged or required to make referrals to the joint venture;
—Participants are encouraged or required to divest their ownership interest if they fail to sustain an ''acceptable'' level of referrals;
—The venture (or its participants) tracks its sources of referrals and distributes this information to the participants; or
—The investment interests are nontransferable or subject to transfer restrictions related to referrals.

• *The manner in which the joint venture is structured.* The structure of the joint venture is suspect if a participant is already engaged in the line of business to be conducted by the joint venture, and that participant will own all or most of the equipment, provide or perform all or most of the items or services, or take responsibility for all or most of the day-to-day operations. With this kind of structure, the co-participant's primary contribution is typically as a captive referral base.

• *The manner in which the investments are financed and profits are distributed.* The existence of one or more of the following indicators suggests that the joint venture may be a vehicle to disguise referrals:

—Participants are offered investment shares for a nominal or no capital contribution;
—The amount of capital that participants invest is disproportionately small, and the returns on the investment are disproportionately large, when compared to a typical investment in a new business enterprise;
—Participants are permitted to borrow their capital investments from another participant or from the joint venture, and to pay back the loan through deductions from profit distributions, thus eliminating even the need to contribute cash;
—Participants are paid extraordinary returns on the investment in comparison with the risk involved; or
—A substantial portion of the gross revenues of the venture are derived from participant-driven referrals.

In light of the obvious risk inherent in joint ventures, whenever possible, hospitals should structure joint ventures to fit squarely in one of the following safe harbors for investment interests:

• The ''small entity'' investment safe harbor (42 CFR 1001.952(a)(2)), which applies to returns on investments as long as no more than 40 percent of the investment interests are held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the venture (interested investors), no more than 40 percent of revenues come from referrals or business otherwise generated from investors, and all other conditions are satisfied;[44]

• The safe harbor for investment interests in an entity located in an underserved area (42 CFR 1001.952(a)(3)), which applies to ventures located in medically underserved areas (as defined in regulations issued by the Department and set forth at 42 CFR part 51c), as long as no more than 50 percent of the investment interests are held by interested investors and all other conditions are satisfied; or

• The hospital-physician ambulatory surgical center (ASC) safe harbor (42 CFR 1001.952(r)(4)). This safe harbor only protects investments in Medicare-certified ASCs owned by hospitals and certain qualifying physicians. Importantly, it does *not* protect

[43] *See* 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the **Federal Register** (59 FR 65372; December 19,1994) and available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.*

[44] There is also a safe harbor for investment interests in large entities (*i.e.,* entities with over fifty million dollars in assets) (42 CFR 1001.952(a)(1)).

investments by hospitals and physicians in non-ASC clinical joint ventures, including, for example, cardiac catheterization or vascular laboratories, oncology centers, and dialysis facilities. Investors in such clinical ventures should look to other safe harbors and to the factors noted above.

These safe harbors protect remuneration in the form of returns on investment interests (*i.e.*, money paid by an entity to its owners or investors as dividends, profit distributions, or the like). However, they do not protect payments made by participating investors to a venture or payments made by the venture to other parties, such as vendors, contractors, or employees (although in some cases these arrangements may fit in other safe harbors).

As we originally observed in our 1989 Special Fraud Alert on Joint Venture Arrangements,[45] joint ventures may take a variety of forms, including a contractual arrangement between two or more parties to cooperate in a common and distinct enterprise providing items or services, thereby creating a ''contractual joint venture.'' We elaborated more fully on contractual joint ventures in our 2003 Special Advisory Bulletin on Contractual Joint Ventures.[46] Contractual joint ventures pose the same kinds of risks as equity joint ventures and should be analyzed similarly. Factors to consider include, for example, whether the hospital is expanding into a new line of business created predominately or exclusively to serve the hospital's existing patient base, whether a would-be competitor of the new line of business is providing all or most of the key services, and whether the hospital assumes little or no *bona fide* business risk. An example of a potentially problematic contractual joint venture would be a hospital contracting with an existing durable medical equipment (DME) supplier to operate the hospital's newly formed DME subsidiary (with its own DME supplier number) on essentially a turnkey basis, with the hospital primarily furnishing referrals and assuming little or no business risk.[47]

Hospitals should be aware that, for reasons described in our 2003 Special Advisory Bulletin on Contractual Joint Ventures,[48] safe harbor protection may not be available for contractual joint ventures, and attempts to carve out separate contracts and qualify each separately for safe harbor protection may be ineffectual and leave the parties at risk under the statute.[49]

If a hospital is planning to participate, directly or indirectly, in a joint venture involving referring physicians and the venture does not qualify for safe harbor protection, the hospital should scrutinize the venture with care, taking into account the factors noted above, and consider obtaining advice from an experienced attorney. At a minimum, to reduce (but not necessarily eliminate) the risk of abuse, hospitals should consider (i) barring physicians employed by the hospital or its affiliates from referring to the joint venture; (ii) taking steps to ensure that medical staff and other affiliated physicians are not encouraged in any manner to refer to the joint venture; (iii) notifying physicians annually in writing of the preceding policy; (iv) refraining from tracking in any manner the volume of referrals attributable to particular referrals sources; (v) ensuring that no physician compensation is tied in any manner to the volume or value of referrals to, or other business generated for, the venture; (vi) disclosing all financial interests to patients; [50] and (vii) requiring that other participants in the joint venture adopt similar steps.

b. Compensation Arrangements With Physicians

Hospitals enter into a variety of compensation arrangements with physicians whereby physicians provide items or services to, or on behalf of, the hospital. Conversely, in some arrangements, hospitals provide items or services to physicians. Examples of these compensation arrangements include, without limitation, medical director agreements, personal or management services agreements, space or equipment leases, and agreements for the provision of billing, nursing, or other staff services. Although many compensation arrangements are legitimate business arrangements, compensation arrangements *may* violate the anti-kickback statute if *one* purpose of the arrangement is to compensate physicians for past or future referrals.[51]

The general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon an arm's-length transaction and should not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties. Arrangements under which hospitals (i) provide physicians with items or services for free or less than fair market value, (ii) relieve physicians of financial obligations they would otherwise incur, or (iii) inflate compensation paid to physicians for items or services pose significant risk. In such circumstances, an inference arises that the remuneration may be in exchange for generating business.

In particular, hospitals should review their physician compensation arrangements and carefully assess the risk of fraud and abuse using the following factors, among others:

- Are the items and services obtained from a physician legitimate, commercially reasonable, and necessary to achieve a legitimate business purpose of the hospital (apart from obtaining referrals)? Assuming that the hospital needs the items and services, does the hospital have multiple arrangements with different physicians, so that in the aggregate the items or services provided by all physicians exceed the hospital's actual needs (apart from generating business)?
- Does the compensation represent fair market value in an arm's-length transaction for the items and services? Could the hospital obtain the services from a non-referral source at a cheaper rate or under more favorable terms? Does the remuneration take into

[45] *See* 1989 Special Fraud Alert on Joint Venture Arrangements, *supra* note 43.

[46] This Special Advisory Bulletin is available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf.*

[47] Contractual ventures with existing clinical laboratories and outpatient therapy providers, among others, are also potentially problematic, particularly if the venture is functionally a turnkey operation that enables a hospital to use its captive referrals to expand into a new line of business with little or no contribution of resources or assumption of real risk.

[48] *See* 2003 Special Advisory Bulletin on Contractual Joint Ventures, *supra* note 46.

[49] The Medicare program permits hospitals to furnish services ''under arrangements'' with other providers or suppliers. Hospitals frequently furnish services ''under arrangements'' with an entity owned, in whole or in part, by referring physicians. Standing alone, these ''under arrangements'' relationships do not fall within the scope of problematic contractual joint ventures described in the Special Fraud Alert; however, these relationships will violate the anti-kickback statute if remuneration is purposefully offered or paid to induce referrals (*e.g.*, paying above-market rates for the services to influence referrals or otherwise tying the arrangements to referrals in any manner). These ''under arrangements'' relationships should be structured, when possible, to fit within an anti-kickback safe harbor. They *must* fit within a Stark exception, even if the service furnished ''under arrangements'' is not itself a DHS. *See* 66 FR 856, 941–2 (January 4, 2001); 69 FR 16054, 16106 (March 26, 2004).

[50] While disclosure to patients does not offer sufficient protection against Federal health care program abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.

[51] As previously noted, a hospital should ensure that each compensation arrangement with a referring physician fits squarely in a statutory or regulatory exception to the Stark law.

account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties? Is the compensation tied, directly or indirectly, to Federal health care program reimbursement?

• Is the determination of fair market value based upon a reasonable methodology that is uniformly applied and properly documented? If fair market value is based on comparables, the hospital should ensure that the market rate for the comparable services is not distorted (*e.g.,* the market for ancillary services may be distorted if all providers of the service are controlled by physicians).

• Is the compensation commensurate with the fair market value of a physician with the skill level and experience reasonably necessary to perform the contracted services?

• Were the physicians selected to participate in the arrangement in whole or in part because of their past or anticipated referrals?

• Is the arrangement properly and fully documented in writing? Are the physicians documenting the services they provide? Is the hospital monitoring the services?

• In the case of physicians staffing hospital outpatient departments, are safeguards in place to ensure that the physicians do not use hospital outpatient space, equipment, or personnel to conduct their private practices? In addition, physicians working in outpatient departments must bill the appropriate site-of-service modifier. The hospital should take reasonable steps to ensure that physicians are aware of this requirement and should take appropriate action if it identifies physicians engaging in improper site-of-service billing.

Whenever possible, hospitals should structure their compensation arrangements with physicians to fit in a safe harbor. Potentially applicable are the space rental safe harbor (42 CFR 1001.952(b)), the equipment rental safe harbor (42 CFR 1001.952(c)), the personal services and management contracts safe harbor (42 CFR 1001.952(d)), the sale of practice safe harbor (42 CFR 1001.952(e)), the referral services safe harbor (42 CFR 1001.952(f)), the employee safe harbor (42 CFR 1001.952(i)), the practitioner recruitment safe harbor (42 CFR 1001.952(n)), and the obstetrical malpractice insurance subsidies safe harbor (42 CFR 1001.952(o)). *An arrangement must fit squarely in a safe harbor to be protected.* Arrangements that do not fit in a safe harbor should be reviewed in light of the totality of all facts and circumstances. At minimum, hospitals should develop policies and procedures requiring physicians to document, and the hospital to monitor, the services or items provided under compensation arrangements (including, for example, by using written time reports). In some cases, particularly rentals, hospitals should consider obtaining an independent fair market valuation using appropriate health care valuation standards.

Arrangements between hospitals and traditional hospital-based physicians (*e.g.,* anesthesiologists, radiologists, and pathologists) raise some different concerns.[52] In these arrangements, it is typically the hospitals that are in a position to influence the flow of business to the physicians, rather than the physicians making referrals to the hospitals.[53] Such arrangements may violate the anti-kickback statute if the hospital solicits or receives something of value—or the physicians offer or pay something of value—in exchange for access to the hospital's Federal health care program business. Illegal kickbacks between hospitals and hospital-based physicians may take a variety of forms, including, without limitation:

• A hospital requiring physicians to pay more than the fair market value for services provided to the hospital-based physicians by the hospital; or

• A hospital compensating physicians less than the fair market value for goods or services provided to the hospital by the physicians.

Accordingly, arrangements that require physicians to provide Medicare Part A supervision and management services for token or no payment in exchange for the ability to provide physician-billable Medicare Part B services at the hospital potentially violate the anti-kickback statute and should be closely scrutinized.

We are aware that hospitals have long provided for the delivery of certain hospital-based physician services through the grant of an *exclusive* contract to a physician or physician group, which includes management, staffing, and other administrative functions, and in some cases limited clinical duties. These exclusive arrangements affect the cash and non-cash value of the overall arrangement to the respective parties.

Depending on the circumstances, an exclusive contract can have substantial value to the hospital-based physician or group, as well as to the hospital, that may well have nothing to do with the value or volume of business flowing between the hospital and the physicians. By way of example only, an exclusive arrangement may reduce the costs a physician or group would otherwise incur for business development and may eliminate administrative costs otherwise incurred by the hospital. In an appropriate context, an exclusive arrangement that requires a hospital-based physician or physician group to perform *reasonable* administrative or *limited* clinical duties *directly related* to the hospital-based professional services at no or a reduced charge would not violate the anti-kickback statute, provided that the overall arrangement is consistent with fair market value in an arm's-length transaction, taking into account the value attributable to the exclusivity. Depending on the circumstances, examples of directly-related administrative or clinical duties include, without limitation: participation on hospital committees, tumor boards, or similar hospital entities; participation in on-call rotation; and performance of quality assurance and oversight activities. Notwithstanding, whether the scope and volume of the required services in a particular arrangement reasonably reflect the value of the exclusivity will depend on the facts and circumstances of the arrangement.

Nothing in this supplemental CPG should be construed as requiring hospital-based physicians to perform administrative or clinical services at no or a reduced charge. Uncompensated or below-market arrangements for goods or services will be subject to close scrutiny for compliance with the statute.

c. Relationships With Other Health Care Entities

As addressed in the preceding subsection, hospitals may obtain referrals of Federal health care program business from a variety of health care professionals and entities. In addition, when furnishing inpatient, outpatient, and related services, hospitals often direct or influence referrals for items

[52] Arrangements between hospitals and hospital-based physicians were the topic of a Management Advisory Report (MAR) titled ''Financial Arrangements Between Hospitals and Hospital-Based Physicians,'' OEI–09–89–00330, available on our Web page at *http://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf.*

[53] In this regard, arrangements between hospitals and traditional hospital-based physicians generally do not pose the same potential to cause the harms typically associated with kickback schemes. Moreover, a hospital's attending medical staff's quality expectations and a hospital's liability exposure for the malpractice of hospital-based physicians constrain the hospital's choice of a hospital-based physician or group. Finally, to the extent that any qualified group can bid for hospital-based business and the request for proposals clearly includes the entire arrangement, the competition is not unfair. (Of course, an open, competitive bidding process does not protect an otherwise illegal kickback arrangement.)

and services reimbursable by Federal health care programs. For example, hospitals may refer patients to, or order items or services from, home health agencies,[54] skilled nursing facilities, durable medical equipment companies, laboratories, pharmaceutical companies, and other hospitals. In cases where a hospital is the referral source for other providers or suppliers, it would be prudent for the hospital to scrutinize carefully any remuneration flowing to the hospital from the provider or supplier to ensure compliance with the anti-kickback statute, using the principles outlined above. Remuneration may include, for example, free or below-market-value items and services or the relief of a financial obligation.

Hospitals should also review their managed care arrangements to ensure compliance with the anti-kickback statute. Managed care arrangements that do not fit within one of the managed care and risk sharing safe harbors at 42 CFR 1001.952(m), (t), or (u) must be evaluated on a case-by-case basis.

d. Recruitment Arrangements

Many hospitals provide incentives to recruit a physician or other health care professional to join the hospital's medical staff and provide medical services to the surrounding community. When used to bring needed physicians to an underserved community, these arrangements can benefit patients. However, recruitment arrangements pose substantial fraud and abuse risk.

In most cases, the recruited physician establishes a private practice in the community instead of becoming a hospital employee.[55] Such arrangements potentially implicate the anti-kickback statute if one purpose of the recruitment arrangement is to induce referrals to the recruiting hospital. Safe harbor protection is available for certain recruitment arrangements offered by hospitals to attract primary care physicians and practitioners to health professional shortage areas (HPSAs), as defined in regulations issued by the Department.[56] The scope of this safe harbor is very limited. In particular, the safe harbor does not protect (a) recruitment arrangements in areas that are not designated as HPSAs, (b) recruitment of specialists, or (c) joint recruitment with existing physician practices in the area.

Because of the significant risk of fraud and abuse posed by improper recruitment arrangements, hospitals should scrutinize these arrangements with care. When assessing the degree of risk associated with recruitment arrangements, hospitals should examine the following factors, among others:

- *The size and value of the recruitment benefit.* Does the benefit exceed what is reasonably necessary to attract a qualified physician to the particular community? Has the hospital previously tried and failed to recruit or retain physicians?
- *The duration of payout of the recruitment benefit.* Total benefit payout periods extending longer than three years from the initial recruitment agreement should trigger heightened scrutiny.
- *The practice of the existing physician.* Is the physician a new physician with few or no patients or an established practitioner with a ready stream of referrals? Is the physician relocating from a substantial distance so that referrals are unlikely to follow or is it possible for the physician to bring an established patient base?
- *The need for the recruitment.* Is the recruited physician's specialty necessary to provide adequate access to medically necessary care for patients in the community? Do patients already have reasonable access to comparable services from other providers or practitioners in or near the community? An assessment of community need based wholly or partially on the competitive interests of the recruiting hospital or existing physician practices would subject the recruitment payments to heightened scrutiny under the statute.

Significantly, hospitals should be aware that the practitioner recruitment safe harbor excludes any arrangement that directly or indirectly benefits any existing or potential referral source other than the recruited physician. Accordingly, the safe harbor does *not* protect ''joint recruitment'' arrangements between hospitals and other entities or individuals, such as solo practitioners, group practices, or managed care organizations, pursuant to which the hospital makes payments directly or indirectly to the other entity or individual. These joint recruitment arrangements present a high risk of fraud and abuse and have been the subject of recent government investigations and prosecutions. These arrangements can easily be used as vehicles to disguise payments from the hospital to an existing referral source—typically an existing physician practice—in exchange for the existing practice's referrals to the hospital. Suspect payments to existing referral sources may include, among other things, income guarantees that shift costs from the existing referral source to the recruited physician and overhead and build-out costs funded for the benefit of the existing referral source. Hospitals should review all ''joint recruiting'' arrangements to ensure that remuneration does not inure in whole or in part to the benefit of any party other than the recruited physician.

e. Discounts

Public policy favors open and legitimate price competition in health care. Thus, the anti-kickback statute contains an exception for discounts offered to customers that submit claims to the Federal health care programs, if the discounts are properly disclosed and accurately reported.[57] However, to qualify for the exception, the discount must be in the form of a reduction in the price of the good or service based on an arm's-length transaction. In other words, the exception covers only reductions in the product's price. Moreover, the regulation provides that the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (*i.e.,* a rebate).

In conducting business, hospitals sell and purchase items and services reimbursable by Federal health care programs. Therefore, hospitals should thoroughly familiarize themselves with the discount safe harbor at 42 CFR 1001.952(h). In particular, depending on their role in the arrangement, hospitals should pay attention to the discount safe harbor requirements applicable to ''buyers,'' ''sellers,'' or ''offerors.'' Compliance with the safe harbor is determined separately for each party. In general, hospitals should ensure that all discounts—including rebates—are properly disclosed and accurately reflected on hospital cost reports. If a hospital offers a discount on an item or service to a buyer, it should ensure that the discount is properly disclosed on the invoice or other documentation for the item or service.

[54] When referring to home health agencies and skilled nursing facilities, hospitals must comply with section 1861(ee)(2)(D) and (H) of the Act, requiring that Medicare participating hospitals, as part of the discharge planning process, (i) share with each beneficiary a list of Medicare-certified home health agencies or skilled nursing facilities, as applicable, that serve the beneficiary's geographic area, and (ii) identify any home health agency or skilled nursing facility in which the hospital has a disclosable financial interest or that has a financial interest in the hospital. *See also* 42 CFR 482.43.

[55] When paid pursuant to a properly structured employment arrangement, payments to physicians who become hospital employees may be protected by the employee safe harbor at 42 CFR 1001.952(i).

[56] *See* 42 CFR 1001.952(n).

[57] *See* 42 U.S.C. 1320a–7b(b)(3)(A); 42 CFR 1001.952(h).

The discount safe harbor does not protect a discount offered to one payor but not to the Federal health care programs. Accordingly, in negotiating discounts for items and services paid from a hospital's pocket (such as those reimbursed under the Medicare Part A prospective payment system), the hospital should ensure that there is no link or connection, explicit or implicit, between discounts offered or solicited for that business and the hospital's referral of business billable by the seller directly to Medicare or another Federal health care program. For example, a hospital should not engage in ''swapping'' by accepting from a supplier an unreasonably low price on Part A services that the hospital pays for out of its own pocket in exchange for hospital referrals that are billable by the supplier directly to Part B (*e.g.,* ambulance services). Suspect arrangements include below-cost arrangements or arrangements at prices lower than the prices offered by the supplier to other customers with similar volumes of business, but without Federal health care program referrals.

Hospitals may also receive discounts on items and services purchased through group purchasing organizations (GPOs). Discounts received from a vendor in connection with a GPO to which a hospital belongs should be properly disclosed and accurately reported on the hospital cost reports. Although there is a safe harbor for payments made by a vendor to a GPO as part of an agreement to furnish items or services to a group of individuals or entities (42 CFR 1001.952(j)), the safe harbor does not protect the discount received by the individual or entity.[58]

f. Medical Staff Credentialing

Certain medical staff credentialing practices may implicate the anti-kickback statute.[59] For example, conditioning privileges on a particular number of referrals or requiring the performance of a particular number of procedures, beyond volumes necessary to ensure clinical proficiency, potentially raise substantial risks under the statute. On the other hand, a credentialing policy that *categorically* refuses privileges to physicians with significant conflicts of interest would not appear to implicate the statute in most situations. Whether a particular credentialing policy runs afoul of the anti-kickback statute would depend on the specific facts and circumstances, including the intent of the parties. Hospitals are advised to examine their credentialing practices to ensure that they do not run afoul of the anti-kickback statute. The OIG has solicited comments about, and is considering, whether further guidance in this area is appropriate.[60]

g. Malpractice Insurance Subsidies

The OIG historically has been concerned that a hospital's subsidy of malpractice insurance premiums for potential referral sources, including hospital medical staff, may be suspect under the anti-kickback statute, because the payments may be used to influence referrals. The OIG has established a safe harbor for medical malpractice premium subsidies provided to obstetrical care practitioners in health professional shortage areas.[61] Depending on the circumstances, premium support may also be structured to fit in other safe harbors.

We are aware of the current disruption (*i.e.,* dramatic premium increases, insurers' withdrawals from certain markets, and/or sudden termination of coverage based upon factors other than the physicians' claims history) in the medical malpractice liability insurance markets in some geographic areas.[62] Notwithstanding, hospitals should review malpractice insurance subsidy arrangements closely to ensure that there is no improper inducement to referral sources. Relevant factors include, without limitation:

- Whether the subsidy is being provided on an interim basis (*e.g.,* until an unrelated insurer is commercially available) for a reasonable fixed period in a geographic area experiencing severe access or affordability problems;
- Whether the subsidy is being offered only to current active medical staff (or physicians new to the locality or in practice less than a year, *i.e.*, physicians with no or few established patients);
- Whether the criteria for receiving a subsidy is unrelated to the volume or value of referrals or other business generated by the subsidized physician or his practice;
- Whether physicians receiving subsidies are paying at least as much as they currently pay for malpractice insurance (*i.e.,* are windfalls to physicians avoided);
- Whether physicians are required to perform services or relinquish rights, which have a value equal to the fair market value of the insurance assistance; and
- Whether the insurance is available regardless of the location at which the physician provides services, including, but not limited to, other hospitals.

No one of these factors is determinative, and this list is illustrative, not exhaustive, of potential considerations in connection with the provision of malpractice insurance subsidies. Parties contemplating malpractice subsidy programs that do not fit into one of the safe harbors may want to consider obtaining an advisory opinion. Parties should also be mindful that these subsidy arrangements also implicate the Stark law.

C. Payments To Reduce or Limit Services: Gainsharing Arrangements

The CMP set forth in section 1128A(b)(1) of the Act prohibits a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries under the physician's direct care.[63] Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments.[64] The statutory proscription is very broad. The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce

[58] To preclude improper shifting of discounts, the safe harbor excludes GPOs that wholly own their members or have members that are subsidiaries of the parent company that wholly owns the GPO. Hospitals with affiliated GPOs should be mindful of these limitations.

[59] In addition to the anti-kickback statute, hospitals should make sure that their credentialing policies comply with all other applicable Federal and State laws and regulations, some of which may prohibit or limit economic credentialing.

[60] *See* our ''Solicitation of New Safe Harbors and Special Fraud Alerts'' (67 FR 72894; December 9, 2002), available on our Web page at *http://oig.hhs.gov/authorities/docs/solicitationannsafeharbor.pdf.*

[61] *See* 42 CFR 1001.952(o).

[62] *See* the OIG's letter on a hospital corporaiton's medical malpractice insurance assistance program, available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf*

[63] The prohibition applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries. *See* section 1128A(b)(1)(A) of the Act. *See also* our August 19, 1999 letter regarding ''Social Security Act sections 1128A(b)(1) and (2) and hospital-physician incentive plans for Medicare or Medicaid beneficiaries enrolled in managed care plans,'' available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm.*

[64] *See* sections 1128A(b)(1)(B) and (b)(2) of the Act.

or limit clinical services directly or indirectly violates the statute.

We are aware that a number of hospitals are engaged in, or considering entering into, incentive arrangements commonly called ''gainsharing.'' While there is no fixed definition of a ''gainsharing'' arrangement, the term typically refers to an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts. We recognize that, properly structured, gainsharing arrangements can serve legitimate business and medical purposes, such as increasing efficiency, reducing waste, and, thereby, potentially increasing a hospital's profitability. However, the plain language of section 1128A(b)(1) of the Act prohibits tying the physicians' compensation for services to reductions or limitations in items or services provided to patients under the physicians' clinical care.[65]

In addition to the CMP risks described above, gainsharing arrangements can also implicate the anti-kickback statute if the cost-savings payments are used to influence referrals. For example, the statute is potentially implicated if a gainsharing arrangement is intended to influence physicians to ''cherry pick'' healthy patients for the hospital offering gainsharing payments and steer sicker (and more costly) patients to hospitals that do not offer gainsharing payments. Similarly, the statute may be implicated if a hospital offers a cost-sharing program with the intent to foster physician loyalty and attract more referrals. In addition, we have serious concerns about overly broad arrangements under which a physician continues for an extended time to reap the benefits of previously-achieved savings or receives cost-savings payments unrelated to anything done by the physician, whether work, services, or other undertaking (*e.g.,* a change in the way the physician practices).

Wherever possible, hospitals should consider structuring cost-saving arrangements to fit in the personal services safe harbor. However, in many cases, protection under the personal services safe harbor is not available because gainsharing arrangements typically involve a percentage payment (*i.e.,* the aggregate fee will not be set in advance, as required by the safe harbor). Finally, gainsharing arrangements may also implicate the Stark law.

[65] A detailed discussion of gainsharing can be found in our July 1999 Special Advisory Bulletin titled ''Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries,'' available on our Web page at *http://oig.hhs.gov/fraud/docs/altersandbulletins/gainsh.htm.*

D. Emergency Medical Treatment and Labor Act (EMTALA)

Hospitals should review their obligations under EMTALA (section 1867 of the Act) to evaluate and treat individuals who come to their emergency departments and, in some circumstances, other facilities. Hospitals should pay particular attention to when an individual must receive a medical screening exam to determine whether that individual is suffering from an emergency medical condition. When such a screening or treatment of an emergency medical condition is required, it cannot be delayed to inquire about an individual's method of payment or insurance status. If the hospital's emergency department (ED) is ''on diversion'' and an individual comes to the ED for evaluation or treatment of a medical condition, the hospital is required to provide such services despite its diversionary status.

Generally, hospital emergency departments may not transfer an individual with an unstable emergency medical condition unless a physician certifies that the benefits outweigh the risks. In such circumstances, the hospital must provide stabilizing treatment to minimize the risks of transfer. Further, the hospital must ensure that the receiving facility has available space and qualified personnel to treat the individual and has agreed to accept transfer of that individual. Moreover, certain medical records must accompany the individual and a hospital that has specialized capabilities or facilities must accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.

A hospital must provide appropriate screening and treatment services within the full capabilities of its staff and facilities. This includes access to specialists who are on call. Thus, hospital policies and procedures should be clear on how to access the full services of the hospital, and all staff should understand the hospital's obligations to individuals under EMTALA. In particular, on-call physicians need to be educated as to their responsibilities under EMTALA, including the responsibility to accept appropriately transferred individuals from other facilities. In addition, all persons working in emergency departments should be periodically trained and reminded of the hospital's EMTALA obligations and hospital policies and procedures designed to ensure that such obligations are met.

For further information about EMTALA, hospitals are directed to: (i) The EMTALA statute at section 1867 of the Act; (ii) the EMTALA statute's implementing regulations at 42 CFR part 489; (iii) our 1999 Special Advisory Bulletin on the Patient Anti-Dumping Statute (64 FR 61353; November 10, 1999), available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/frdump.pdf;* and (iv) CMS's EMTALA resource Web page located at *http://www.cms.gov/providers/emtala/emtala.asp.*

E. Substandard Care

The OIG has authority to exclude any individual or entity from participation in Federal health care programs if the individual or entity provides unnecessary items or services (*i.e.,* items or services in excess of the needs of a patient) or substandard items or services (*i.e.,* items or services of a quality which fails to meet professionally recognized standards of health care).[66] Significantly, neither knowledge nor intent is required for exclusion under this provision. The exclusion can be based upon unnecessary or substandard items or services provided to any patient, even if that patient is not a Medicare or Medicaid beneficiary.

We are mindful that the vast majority of hospitals are fully committed to providing quality care to their patients. To achieve their quality-related goals, hospitals should continually measure their performance against comprehensive standards. Medicare participating hospitals must meet all of the Medicare hospital conditions of participation (COPs), including without limitation, the COP pertaining to a quality assessment and performance improvement program at 42 CFR 482.21 and the hospital COP pertaining to the medical staff at 42 CFR 482.22. Compliance with the COPs is determined by State survey agencies or accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association. In addition, hospitals should develop their own quality of care protocols and implement mechanisms for evaluating compliance with those protocols.

In reviewing the quality of care provided, hospitals must not limit their review to the quality of their nursing and other ancillary services. Hospitals must monitor the quality of medical

[66] *See* section 1128(b)(6)(B) of the Act, which is available through the Internet at *http://www4.law.cornell.edu/uscode/42/1320a-7.html.*

services provided at the hospital by appropriately overseeing the credentialing and peer review of their medical staffs.

F. Relationships With Federal Health Care Beneficiaries

Hospitals' relationships with Federal health care beneficiaries may also implicate the fraud and abuse laws. In particular, hospitals should be aware that section 1128A(a)(5) of the Act authorizes the OIG to impose CMPs on hospitals (and others) that offer or transfer remuneration to a Medicare or Medicaid beneficiary that the offeror knows or should know is likely to influence the beneficiary to order or receive items or services from a particular provider, practitioner, or supplier for which payment may be made under the Medicare or Medicaid programs. The definition of ''remuneration'' expressly includes the offer or transfer of items or services for free or other than fair market value, including the waiver of all or part of a Medicare or Medicaid cost-sharing amount.[67] In other words, hospitals may not offer valuable items or services to Medicare or Medicaid beneficiaries to attract their business. In this regard, hospitals should familiarize themselves with the OIG's August 2002 Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries.[68]

1. Gifts and Gratuities

Hospitals should scrutinize any offers of gifts or gratuities to beneficiaries for compliance with the CMP provision prohibiting inducements to Medicare and Medicaid beneficiaries. The key inquiry under the CMP is whether the remuneration is something that the hospital knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for Medicare or Medicaid payable services. As interpreted by the OIG, section 1128A(a)(5) of the Act does not apply to the provision of items or services valued at less than $10 per item and $50 per patient in the aggregate on an annual basis.[69] A special exception for incentives to promote the delivery of preventive care services is discussed below at section II.I.2.

2. Cost-Sharing Waivers

In general, hospitals are obligated to collect cost-sharing amounts owed by Federal health care program beneficiaries. Waiving owed amounts may constitute prohibited remuneration to beneficiaries under section 1128A(a)(5) of the Act or the anti-kickback statute. Certain waivers of Part A inpatient cost-sharing amounts may be protected by structuring them to fit in the safe harbor for waivers of beneficiary inpatient coinsurance and deductible amounts at 42 CFR 1001.952(k). In particular, under the safe harbor, waived amounts may not be claimed as bad debt; the waivers must be offered uniformly across the board without regard to the reason for admission, length of stay, or DRG; and waivers may not be made as part of any agreement with a third party payer, unless the third party payer is a Medicare SELECT plan under section 1882(t)(1) of the Act.[70]

In addition, hospitals (and others) may waive cost-sharing amounts on the basis of a beneficiary's financial need, so long as the waiver is not routine, not advertised, and made pursuant to a good faith, individualized assessment of the beneficiary's financial need or after reasonable collection efforts have failed.[71] The OIG recognizes that what constitutes a good faith determination of ''financial need'' may vary depending on the individual patient's circumstances and that hospitals should have flexibility to take into account relevant variables. These factors may include, for example:

- The local cost of living;
- A patient's income, assets, and expenses;
- A patient's family size; and
- The scope and extent of a patient's medical bills.

Hospitals should use a reasonable set of financial need guidelines that are based on objective criteria and appropriate for the applicable locality. The guidelines should be applied uniformly in all cases. While hospitals have flexibility in making the determination of financial need, we do not believe it is appropriate to apply inflated income guidelines that result in waivers for beneficiaries who are not in genuine financial need. Hospitals should consider that the financial status of a patient may change over time and should recheck a patient's eligibility at reasonable intervals sufficient to ensure that the patient remains in financial need. For example, a patient who obtains outpatient hospital services several times a week would not need to be rechecked every visit. Hospitals should take reasonable measures to document their determinations of Medicare beneficiaries' financial need. We are aware that in some situations patients may be reluctant or unable to provide documentation of their financial status. In those cases, hospitals may be able to use other reasonable methods for determining financial need, including, for example, documented patient interviews or questionnaires.

In sum, hospitals should review their waiver policies to ensure that the policies and the manner in which they are implemented comply with all applicable laws. For more information about cost-sharing waivers, hospitals should review our February 2, 2004 paper on ''Hospital Discounts Offered To Patients Who Cannot Afford To Pay Their Hospital Bills,'' containing a section titled ''Reductions or Waivers of Cost-Sharing Amounts for Medicare Beneficiaries Experiencing Financial Hardship'' and available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf.*[72]

3. Free Transportation

The plain language of the CMP prohibits offering free transportation to Medicare or Medicaid beneficiaries to influence their selection of a particular provider, practitioner, or supplier. Notwithstanding, hospitals can offer free local transportation of *low* value (*i.e.*, within the $10 per item and $50 annual limits).[73] Luxury and specialized transportation, such as limousines or ambulances, would exceed the low value threshold and are problematic, as are arrangements tied in any manner to the volume or value of referrals and arrangements tied to particularly lucrative treatments or medical conditions. However, we have indicated that we are considering developing a regulatory exception for some complimentary local transportation provided to beneficiaries residing in a

[67] *See* section 1128A(i)(6) of the Act.

[68] The Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (67 FR 55855; August 30, 2002) is available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.*

[69] *See id.*

[70] The OIG has proposed a rule to extend this safe harbor to protect waivers of Part B cost-sharing amounts pursuant to agreements with Medicare SELECT plans. *See* 67 FR 60202 (September 25, 2002), available on our Web page at *http://oig.hhs.gov/fraud/docs/safeharborregulations/MedicareSELECTNPRMFederalRegister.pdf.* However, the OIG is still considering comments on this rule, and it has not been finalized.

[71] *See* section 1128A(i)(6)(A) of the Act.

[72] *See also* the OIG's Special Fraud Alert on Routine Waiver of Copayments or Deductibles Under Medicare Part B, issued May 1991, republished in the **Federal Register** at 59 FR 65372, 65374 (December 19, 1994), and available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.*

[73] Our position on local transportation of nominal value is more fully set forth in the preamble to the final rule enacting 42 CFR 1003.102(b)(13). *See* 65 FR 24400, 24411 (April 26, 2000).

hospital's primary service area.[74] Accordingly, until such time as we promulgate a final rule on complimentary local transportation under section 1128A(a)(5) of the Act or indicate our intention not to proceed with such rule, we have indicated that we will not impose administrative sanctions for violations of section 1128A(a)(5) of the Act in connection with hospital-based complimentary transportation programs that meet the following conditions:

- The program was in existence prior to August 30, 2002, the date of publication of the Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries.
- Transportation is offered uniformly and without charge or at reduced charge to all patients of the hospital or hospital-owned ambulatory surgical center (and may also be made available to their families).
- The transportation is only provided to and from the hospital or a hospital-owned ambulatory surgical center and is for the purpose of receiving hospital or ambulatory surgical center services (or, in the case of family members, accompanying or visiting hospital or ambulatory surgical center patients).
- The transportation is provided only within the hospital's or ambulatory surgical center's primary service area.
- The costs of the transportation are not claimed directly or indirectly by any Federal health care program cost report or claim and are not otherwise shifted to any Federal health care program.
- The transportation does not include ambulance transportation.

Other arrangements are subject to a case-by-case review under the statute to ensure that no improper inducement exists.

G. HIPAA Privacy and Security Rules

As of April 14, 2003, all hospitals that conduct electronic transactions for which standards have been adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) were required to comply with the Privacy Rule promulgated pursuant to HIPAA. Generally, the HIPAA Privacy Rule addresses the use and disclosure of individuals' identifiable health information (protected health information or PHI) by covered hospitals and other covered entities, as well as standards for individuals' privacy rights to understand and control how their health information is used. The Privacy Rule (45 CFR parts 160 and 164, subparts A and E) and other helpful information about how it applies, including frequently asked questions, can be found on the Web page of the Department's Office for Civil Rights (OCR) at *http://www.hhs.gov/ocr/hipaa/.* Questions about the privacy rule should be submitted to OCR. Hospitals can contact OCR by following the instructions on its Web page, *http://www.hhs.gov/ocr/contact.html,* or by calling the HIPAA toll-free number, (866) 627–7748.

To ease the burden of complying with the new requirements, the Privacy Rule gives covered hospitals and other covered entities some flexibility to create their own privacy procedures. Each hospital should make sure that it is compliant with all applicable provisions of the Privacy Rule, including provisions pertaining to required disclosures (such as required disclosures to the Department when it is undertaking a Privacy Rule investigation or compliance review) in developing its privacy procedures that are tailored to fit its particular size and needs.

The final HIPAA Security Rule (45 CFR parts 160 and 164, subparts A and C) was published in the **Federal Register** on February 20, 2003. It is available on CMS's Web page at *http://www.cms.gov/hipaa/hipaa2.* The Security Rule specifies a series of administrative, technical, and physical security safeguards for hospitals that are covered entities and other covered entities to use to assure, among other provisions, the confidentiality of electronic PHI. Hospitals that are covered entities must be compliant with the Security Rule by April 20, 2005. The Security Rule requirements are flexible and scalable, which allows each covered entity to tailor its approach to compliance based on its own unique circumstances. Covered entities can consider their organization and capabilities, as well as costs, in designing their security plans and procedures. Questions about the HIPAA Security Rule should be submitted to CMS. Hospitals can contact CMS by following the instructions on its Web page, *http://www.cms.gov/hipaa/hipaa2/contact,* or by calling the HIPAA toll-free number, (866) 627–7748.

H. Billing Medicare or Medicaid Substantially in Excess of Usual Charges

Section 1128(b)(6)(A) of the Act provides for the permissive exclusion from Federal health care programs of any provider or supplier that submits a claim *based on costs or charges* to the Medicare or Medicaid programs that is ''substantially in excess'' of its usual charge or cost, unless the Secretary finds there is ''good cause'' for the higher charge or cost. The exclusion provision does not require a provider to charge everyone the same price; nor does it require a provider to offer Medicare or Medicaid its ''best price.'' However, providers cannot routinely charge Medicare or Medicaid substantially more than they usually charge others. Hospitals have raised concerns regarding the impact of the exclusion authority on hospital services, and the OIG is considering those concerns in the context of the rulemaking process.[75] The OIG's policy regarding application of the exclusion authority to discounts offered to uninsured and underinsured patients is discussed below.

I. Areas of General Interest

Although in most cases the following areas do not pose significant fraud and abuse risk, the OIG has received numerous inquiries from hospitals and others on these topics. Therefore, we offer the following guidance to assist hospitals in their review of these arrangements.

1. Discounts to Uninsured Patients

No OIG authority, including the Federal anti-kickback statute, prohibits or restricts hospitals from offering discounts to uninsured patients who are unable to pay their hospital bills.[76] In addition, the OIG has never excluded or attempted to exclude any provider or supplier for offering discounts to uninsured or underinsured patients under the permissive exclusion authority at section 1128(b)(6)(A) of the Act. However, to provide additional assurance to the industry, the OIG recently proposed regulations that would define key terms in the statute.[77] Among other things, the proposed regulations would make clear that free or substantially reduced charges to

[74] *See supra* note 68.

[75] *See* Notice of Proposed Rulemaking regarding ''Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges'' (68 FR 53939; September 15, 2003), available on our Web page at *http://oig.hhs.gov/authorities/docs/FRSIENPRM.pdf.*

[76] Discounts offered to *underinsured* patients potentially raise a more significant concern under the anti-kickback statute, and hospitals should exercise care to ensure that such discounts are not tied directly or indirectly to the furnishing of items or services payable by a Federal health care program. For more information, *see* our February 2, 2004 paper on ''Hospital Discounts Offered To Patients Who Cannot Afford To Pay Their Hospital Bills,'' available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf,* and CMS's paper titled ''Questions On Charges For The Uninsured,'' dated February 17, 2004, and available on CMS's Web page at *http://www.cms.gov/FAQ_Uninsured.pdf.*

[77] *See* 68 FR 53939 (September 15, 2003), available on our Web page at *http://oig.hhs.gov/authorities/docs/FRSIENPRM.pdf.*

uninsured persons would not affect the calculation of a provider's or supplier's ''usual'' charges, as the term ''usual charges'' is used in the exclusion provision. The OIG is currently reviewing the public comments to the proposed regulations. Until such time as a final regulation is promulgated or the OIG indicates its intention not to promulgate a final rule, it will continue to be the OIG's enforcement policy that when calculating their ''usual charges'' for purposes of section 1128(b)(6)(A) of the Act, individuals and entities do not need to consider free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-paying patients for the items or services furnished. In offering such discounts, a hospital should report full uniform charges, rather than the discounted amounts, on its Medicare cost report and make the FI aware that it has reported its full charges.[78]

Under CMS rules, Medicare generally reimburses a hospital for a percentage of its ''bad debt'' (*i.e.*, uncollectible Medicare deductible or coinsurance amounts), but only if the hospital bills the Medicare patient for unpaid amounts first, and engages in reasonable, good faith collection efforts that are consistent with the degree of effort applied to collecting similar debts from non-Medicare patients.[79] However, as explained in CMS's paper titled ''Questions On Charges For The Uninsured,'' a hospital can forgo collection efforts aimed at a Medicare patient, if the hospital, using its customary methods, documents that the patient is indigent or medically indigent[80] and that no source other than the patient is legally responsible for the unpaid deductibles and coinsurance.

CMS Medicare bad debt reimbursement guidelines provide that a hospital should apply its customary indigency criteria to Medicare patients; however, the hospital must document such determination for such patients. To claim Medicare bad debt reimbursement, the hospital must follow the guidance laid out in sections 310, 312, and 322 of the Provider Reimbursement Manual.[81] A hospital should examine a patient's total resources, which could include, but are not limited to, an analysis of assets, liabilities, income, expenses, and any extenuating circumstances that would affect the determination. The hospital should document the method by which it determined the indigency and include all backup information used to substantiate the determination. If, instead of making such a determination, a hospital attempts to collect the outstanding amounts from the Medicare beneficiary, such efforts must be documented in the patient's file with copies of the bill(s), follow-up letters, and reports of telephone and personal contacts. In the case of a dually-eligible patient (*i.e.*, a patient entitled to both Medicare and Medicaid), the hospital should document the bad debt claim by including a denial of payment from the State.

2. Preventive Care Services

Hospitals frequently participate in community-based efforts to deliver preventive care services. The Medicare and Medicaid programs encourage patients to access preventive care services. The prohibition against beneficiary inducements at section 1128A(a)(5) of the Act does not apply to incentives offered to promote the delivery of certain preventive care services, if the programs are structured in accordance with the regulatory requirements at 42 CFR 1003.101. Generally, to fit within the preventive care exception, a service must be a prenatal service or post-natal well-baby visit or a specific clinical service described in the current U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services*[82] that is reimbursed by Medicare or Medicaid. Obtaining the service may not be tied directly or indirectly to the provision of other Medicare or Medicaid services. In addition, the incentives may not be in the form of cash or cash equivalents and may not be disproportionate to the value of the preventive care provided. From an anti-kickback perspective, the chief concern is whether an arrangement to induce patients to obtain preventive care services is intended to induce other business payable by a Federal health care program. Relevant factors in making this evaluation would include, but not be limited to: the nature and scope of the preventive care services; whether the preventive care services are tied directly or indirectly to the provision of other items or services and, if so, the nature and scope of the other services; the basis on which patients are selected to receive the free or discounted services; and whether the patient is able to afford the services.

3. Professional Courtesy

Although historically ''professional courtesy'' referred to the practice of physicians waiving the entire professional fee for other physicians, the term is variously used in the industry now to describe a range of practices involving free or discounted services (including ''insurance only'' billing) furnished to physicians and their families and staff. Some hospitals have used the term ''professional courtesy'' to describe various programs that offer free or discounted hospital services to medical staff, employees, community physicians, and their families and staff. Although many professional courtesy programs are unlikely to pose a significant risk of abuse (and many may be legitimate employee benefits programs eligible for the employee safe harbor), some hospital-sponsored ''professional courtesy'' programs may implicate the fraud and abuse statutes.

In general, whether a professional courtesy program runs afoul of the anti-kickback statute turns on whether the recipients of the professional courtesy are selected in a manner that takes into account, directly or indirectly, any recipient's ability to refer to, or otherwise generate business for, the hospital. Also relevant is whether the physicians have solicited the professional courtesy in return for referrals. With respect to the Stark law, the key inquiry is whether the arrangement fits in the exception for professional courtesy at 42 CFR 411.357(s). Finally, hospitals should evaluate the method by which the courtesy is granted. For example, ''insurance only'' billing offered to a Federal program beneficiary potentially implicates the anti-kickback statute, the False Claims Act, and the CMP

[78] For more information, *see* CMS's paper titled ''Questions On Charges For The Uninsured,'' dated February 17, 2004, and available on CMS's Web page at *http://www.cms.gov/FAQ_Uninsured.pdf*.

[79] *See* 42 CFR 413.89 and Medicare's Provider Reimbursement Manual, Part I, Chapter 3, Section 310, available on CMS's Web page at *http://www.cms.hhs.gov/manuals/pub151/PUB_15_1.asp; see also* Provider Reimbursement Manual, Part II, chapter 11, section 1102.3.L, available on CMS's Web page at *http://www.cms.gov/manuals/pub152/PUB_15_2.asp*.

[80] *See* ''Questions On Charges For The Uninsured,'' dated February 17, 2004 and available on CMS's Web page at *http://www.cms.gov/FAQ_Uninsured.pdf*. In the paper, CMS further explains that hospitals may, but are not required to, determine a patient's indigency using a sliding scale. In this type of arrangement, the provider would agree to deem the patient indigent with respect to a portion of the patient's account (*e.g.*, a flat percentage of the debt based on the patient's income, assets, or the size of the patient's liability relative to income). In the case of a Medicare patient who is determined to be indigent using this method, the amount the hospital decides, pursuant to its policy, not to collect from the patient can be claimed by the provider as Medicare bad debt. The hospital must, however, engage in a reasonable collection effort to collect the remaining balance before claiming such balance as reimbursable bad debt. *Id.*

[81] See Medicare's Provider Reimbursement Manual, Part I, chapter 3, available on CMS's Web page at *http://www.cms.hhs.gov/manuals/pub151/PUB_15_1.asp*.

[82] Available on the Internet at *http://www.ahrq.gov/clinic/cps3dix.htm*.

provision prohibiting inducements to Medicare and Medicaid beneficiaries (discussed in section II.F above). Notably, the Stark law exception for professional courtesy requires that insurers be notified if ''professional courtesy'' includes ''insurance only'' billing.

III. Hospital Compliance Program Effectiveness

Hospitals with an organizational culture that values compliance are more likely to have effective compliance programs and, thus, are better able to prevent, detect, and correct problems. Building and sustaining a successful compliance program rarely follows the same formula from organization to organization. However, such programs generally include: The commitment of the hospital's governance and management at the highest levels; structures and processes that create effective internal controls; and regular self-assessment and enhancement of the existing compliance program. The 1998 CPG provided guidance for hospitals on establishing sound internal controls.[83] This section discusses the important roles of corporate leadership and self-assessment of compliance programs.

A. Code of Conduct

Every effective compliance program necessarily begins with a formal commitment to compliance by the hospital's governing body and senior management. Evidence of that commitment should include active involvement of the organizational leadership, allocation of adequate resources, a reasonable timetable for implementation of the compliance measures, and the identification of a compliance officer and compliance committee vested with sufficient autonomy, authority, and accountability to implement and enforce appropriate compliance measures. A hospital's leadership should foster an organizational culture that values, and even rewards, the prevention, detection, and resolution of problems. Moreover, hospitals' leadership and management should ensure that policies and procedures, including, for example, compensation structures, do not create undue pressure to pursue profit over compliance. In short, the hospital should endeavor to develop a culture that values compliance from the top down and fosters compliance from the bottom up. Such an organizational culture is the foundation of an effective compliance program.

Although a clear statement of detailed and substantive policies and procedures—and the periodic evaluation of their effectiveness—is at the core of a compliance program, the OIG recommends that hospitals also develop a general organizational statement of ethical and compliance principles that will guide the entity's operations. One common expression of this statement of principles is a code of conduct. The code should function in the same fashion as a constitution, *i.e.*, as a document that details the fundamental principles, values, and framework for action within an organization. The code of conduct for a hospital should articulate a commitment to compliance by management, employees, and contractors, and should summarize the broad ethical and legal principles under which the hospital must operate. The Code of Conduct should also include a requirement that professionals follow the ethical standards dictated by their respective professional organizations. Unlike the more detailed policies and procedures, the code of conduct should be brief, easily readable, and cover general principles applicable to all members of the organization.

As appropriate, the OIG strongly encourages the participation and involvement of the hospital's board of directors, officers (including the chief executive officer (CEO)), members of senior management, representatives from the medical and clinical staffs, and other personnel from various levels of the organizational structure in the development of all aspects of the compliance program, especially the code of conduct. Management and employee involvement in this process communicates a strong and explicit commitment by management to foster compliance with applicable Federal health care program requirements. It also communicates the need for all directors, officers, managers, employees, contractors, and medical and clinical staff members to comply with the organization's code of conduct and policies and procedures.

B. Regular Review of Compliance Program Effectiveness

Hospitals should regularly review the implementation and execution of their compliance program elements. This review should be conducted at least annually and should include an assessment of each of the basic elements individually, as well as the overall success of the program. This review should help the hospital identify any weaknesses in its compliance program and implement appropriate changes.

A common method of assessing compliance program effectiveness is measurement of various outcomes indicators (*e.g.*, billing and coding error rates, identified overpayments, and audit results). However, we have observed that exclusive reliance on these indicators may cause an organization to miss crucial underlying weaknesses. We recommend that hospitals examine program outcomes and assess the underlying structure and process of each compliance program element. We have identified a number of factors that may be useful when evaluating the effectiveness of basic compliance program elements. Hospitals should consider these factors, as well as others, when developing a strategy for assessing their compliance programs. While no one factor is determinative of program effectiveness, the following factors are often observed in effective compliance programs.

1. Designation of a Compliance Officer and Compliance Committee

The compliance department is the backbone of the hospital's compliance program. The compliance department should be led by a well-qualified compliance officer, who is a member of senior management, and should be supported by a compliance committee. The purpose of the compliance department is to implement the hospital's compliance program and to ensure that the hospital complies with all applicable Federal health care program requirements. To ensure that the compliance department is meeting this objective, each hospital should conduct an annual review of its compliance department. Some factors that the organization may wish to consider in its evaluation include the following:

- Does the compliance department have a clear, well-crafted mission?
- Is the compliance department properly organized?
- Does the compliance department have sufficient resources (staff and budget), training, authority, and autonomy to carry out its mission?
- Is the relationship between the compliance function and the general counsel function appropriate to achieve the purpose of each?
- Is there an active compliance committee, comprised of trained

[83] Among other things, the 1998 hospital CPG includes a detailed discussion of the structure and processes that make up the recommended seven elements of a compliance program. The seven basic elements of a compliance program are: Designation of a compliance officer and compliance committee; development of compliance policies and procedures, including standards of conduct; development of open lines of communication; appropriate training and education; response to detected offenses; internal monitoring and auditing; and enforcement of disciplinary standards.

representatives of each of the relevant functional departments, as well as senior management?

• Are *ad hoc* groups or task forces assigned to carry out any special missions, such as conducting an investigation or evaluating a proposed enhancement to the compliance program?

• Does the compliance officer have direct access to the governing body, the president or CEO, all senior management, and legal counsel?

• Does the compliance officer have independent authority to retain outside legal counsel?

• Does the compliance officer have a good working relationship with other key operational areas, such as internal audit, coding, billing, and clinical departments?

• Does the compliance officer make regular reports to the board of directors and other hospital management concerning different aspects of the hospital's compliance program?

2. Development of Compliance Policies and Procedures, Including Standards of Conduct

The purpose of compliance policies and procedures is to establish bright-line rules that help employees carry out their job functions in a manner that ensures compliance with Federal health care program requirements and furthers the mission and objective of the hospital itself. Typically, policies and procedures are written to address identified risk areas for the organization. As hospitals conduct a review of their written policies and procedures, some of the following factors may be considered:

• Are policies and procedures clearly written, relevant to day-to-day responsibilities, readily available to those who need them, and re-evaluated on a regular basis?

• Does the hospital monitor staff compliance with internal policies and procedures?

• Have the standards of conduct been distributed to all directors, officers, managers, employees, contractors, and medical and clinical staff members?

• Has the hospital developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?

• Does the risk assessment tool include an evaluation of Federal health care program requirements, as well as other publications, such as the OIG's CPGs, work plans, special advisory bulletins, and special fraud alerts?

3. Developing Open Lines of Communication

Open communication is essential to maintaining an effective compliance program. The purpose of developing open communication is to increase the hospital's ability to identify and respond to compliance problems. Generally, open communication is a product of organizational culture and internal mechanisms for reporting instances of potential fraud and abuse. When assessing a hospital's ability to communicate potential compliance issues effectively, a hospital may wish to consider the following factors:

• Has the hospital fostered an organizational culture that encourages open communication, without fear of retaliation?

• Has the hospital established an anonymous hotline or other similar mechanism so that staff, contractors, patients, visitors, and medical and clinical staff members can report potential compliance issues?

• How well is the hotline publicized; how many and what types of calls are received; are calls logged and tracked (to establish possible patterns); and is the caller informed of the hospital's actions?

• Are all instances of potential fraud and abuse investigated?

• Are the results of internal investigations shared with the hospital governing body and relevant departments on a regular basis?

• Is the governing body actively engaged in pursuing appropriate remedies to institutional or recurring problems?

• Does the hospital utilize alternative communication methods, such as a periodic newsletter or compliance intranet website?

4. Appropriate Training and Education

Hospitals that fail to train and educate their staff adequately risk liability for the violation of health care fraud and abuse laws. The purpose of conducting a training and education program is to ensure that each employee, contractor, or any other individual that functions on behalf of the hospital is fully capable of executing his or her role in compliance with rules, regulations, and other standards. In reviewing their training and education programs, hospitals may consider the following factors:

• Does the hospital provide qualified trainers to conduct annual compliance training for its staff, including both general and specific training pertinent to the staff's responsibilities?

• Has the hospital evaluated the content of its training and education program on an annual basis and determined that the subject content is appropriate and sufficient to cover the range of issues confronting its employees?

• Has the hospital kept up-to-date with any changes in Federal health care program requirements and adapted its education and training program accordingly?

• Has the hospital formulated the content of its education and training program to consider results from its audits and investigations; results from previous training and education programs; trends in hotline reports; and OIG, CMS, or other agency guidance or advisories?

• Has the hospital evaluated the appropriateness of its training format by reviewing the length of the training sessions; whether training is delivered via live instructors or via computer-based training programs; the frequency of training sessions; and the need for general and specific training sessions?

• Does the hospital seek feedback after each session to identify shortcomings in the training program, and does it administer post-training testing to ensure attendees understand and retain the subject matter delivered?

• Has the hospital's governing body been provided with appropriate training on fraud and abuse laws?

• Has the hospital documented who has completed the required training?

• Has the hospital assessed whether to impose sanctions for failing to attend training or to offer appropriate incentives for attending training?

5. Internal Monitoring and Auditing

Effective auditing and monitoring plans will help hospitals avoid the submission of incorrect claims to Federal health care program payors. Hospitals should develop detailed annual audit plans designed to minimize the risks associated with improper claims and billing practices. Some factors hospitals may wish to consider include the following:

• Is the audit plan re-evaluated annually, and does it address the proper areas of concern, considering, for example, findings from previous years' audits, risk areas identified as part of the annual risk assessment, and high volume services?

• Does the audit plan include an assessment of billing systems, in addition to claims accuracy, in an effort to identify the root cause of billing errors?

• Is the role of the auditors clearly established and are coding and audit personnel independent and qualified, with the requisite certifications?

• Is the audit department available to conduct unscheduled reviews and does a mechanism exist that allows the compliance department to request additional audits or monitoring should the need arise?

• Has the hospital evaluated the error rates identified in the annual audits?

• If the error rates are not decreasing, has the hospital conducted a further investigation into other aspects of the hospital compliance program in an effort to determine hidden weaknesses and deficiencies?

• Does the audit include a review of all billing documentation, including clinical documentation, in support of the claim?

6. Response to Detected Deficiencies

By consistently responding to detected deficiencies, hospitals can develop effective corrective action plans and prevent further losses to Federal health care programs. Some factors a hospital may wish to consider when evaluating the manner in which it responds to detected deficiencies include the following:

• Has the hospital created a response team, consisting of representatives from the compliance, audit, and any other relevant functional areas, which may be able to evaluate any detected deficiencies quickly?

• Are all matters thoroughly and promptly investigated?

• Are corrective action plans developed that take into account the root causes of each potential violation?

• Are periodic reviews of problem areas conducted to verify that the corrective action that was implemented successfully eliminated existing deficiencies?

• When a detected deficiency results in an identified overpayment to the hospital, are overpayments promptly reported and repaid to the FI?

• If a matter results in a probable violation of law, does the hospital promptly disclose the matter to the appropriate law enforcement agency? [84]

7. Enforcement of Disciplinary Standards

By enforcing disciplinary standards, hospitals help create an organizational culture that emphasizes ethical behavior. Hospitals may consider the following factors when assessing the effectiveness of internal disciplinary efforts:

• Are disciplinary standards well-publicized and readily available to all hospital personnel?

• Are disciplinary standards enforced consistently across the organization?

• Is each instance involving the enforcement of disciplinary standards thoroughly documented?

• Are employees, contractors and medical and clinical staff members checked routinely (*e.g.*, at least annually) against government sanctions lists, including the OIG's List of Excluded Individuals/Entities (LEIE) [85] and the General Services Administration's Excluded Parties Listing System.

In sum, while no single factor is conclusive of an effective compliance program, the preceding seven areas form a useful starting point for developing and maintaining an effective compliance program.

IV. Self-Reporting

Where the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the hospital should promptly report the existence of misconduct to the appropriate Federal and State authorities [86] within a reasonable period, but not more than 60 days,[87] after determining that there is credible evidence of a violation.[88] Prompt voluntary reporting will demonstrate the hospital's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (*e.g.,* penalties, assessments, and exclusion), if the reporting hospital becomes the subject of an OIG investigation.[89] To encourage providers to make voluntary disclosures, the OIG published the Provider Self-Disclosure Protocol.[90]

When reporting to the government, a hospital should provide all information relevant to the alleged violation of applicable Federal or State law(s)and the potential financial or other impact of the alleged violation. The compliance officer, under advice of counsel and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil, or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the applicable Federal health care programs or their beneficiaries.

V. Conclusion

In today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for health care, it is imperative for hospitals to establish and maintain effective compliance programs. These programs should foster a culture of compliance that begins at the highest levels and extends throughout the organization. This supplemental CPG is intended as a resource for hospitals to help them operate effective compliance programs that decrease errors, fraud, and abuse and increase compliance with Federal health care program requirements for the benefit of the hospitals and public alike.

[FR Doc. 05–1620 Filed 1–27–05; 8:45 am]

BILLING CODE 4150–01–P

[84] For more information on when to self-report, *see* section IV, below.

[85] *See http://oig.hhs.gov/fraud/exclusions.html.* The OIG also makes available Monthly Supplements for Standard LEIE, which can be compared to existing hospital personnel lists.

[86] Appropriate Federal and State authorities include the OIG, CMS, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Food and Drug Administration, the Department's Office for Civil Rights, the Federal Trade Commission, the Drug Enforcement Administration, the Federal Bureau of Investigation, and the other investigative arms for the agencies administering the affected Federal or State health care programs, such as the State Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, the Health Resources and Services Administration, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

[87] In contrast, to qualify for the ''not less than double damages'' provision of the False Claims Act, the provider must provide the report to the government within 30 days after the date when the provider first obtained the information. *See* 31 U.S.C. 3729(a).

[88] Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, the OIG believes a provider should immediately report misconduct that: (i) Is a clear violation of administrative, civil, or criminal laws; (ii) has a significant adverse effect on the quality of care provided to Federal health care program beneficiaries; or (iii) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

[89] The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation pursuant to 42 U.S.C. 1320a–7(b)(7) for violations of various fraud and abuse laws. *See* 62 FR 67392 (December 24, 1997).

[90] *See* 63 FR 58399 (October 30, 1998), available on our Web page at *http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Amended Notice of Meeting

Notice is hereby given of change in the meeting of the NIH Advisory Board for Clinical Research, January 31, 2005, 2 p.m. to January 31, 2005, 5 p.m., National Institutes of Health, Building 10, 10 Center Drive, Medical Board Room 2C116, Bethesda, MD 20892 which was published in the **Federal Register** on January 12, 2005, 70 FR 2177.

The open session will start from 10 a.m.–2 p.m. The closed session will be held from 2 p.m. until adjournment. The meeting will be held in Room 4–2551, CRC Medical Board Room. The meeting is partially Closed to the public.

Dated: January 27, 2005.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–1884 Filed 1–27–05; 4:53 pm]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 the following 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 Cancer Institute Special Emphasis Panel, Breast Cancer Surveillance Consortium.

Date: January 28, 2005.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: EPN–C, 6130 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Timothy C. Meeker, MD, Scientific Review Administrator, Special Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8088, Rockville, MD 20852, 301/594–1279.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: January 24, 2005.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–1682 Filed 1–28–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel, Biological Rhythms and Sleep.

Date: February 9, 2005.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Selmanoff, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892, 301–435–1119, *mselimanoff@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Musculoskeletal Rehabilitation Special Emphasis Panel.

Date: February 15, 2005.

Time: 11:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Daniel F. McDonald, PhD, Chief, Renal and Urological Sciences IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group, Child Psychopathology and Developmental Disabilities Study Section.

Date: February 17–18, 2005.

Time: 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant application.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Karen Sirocco, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–0676, *siroccok@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Urologic and Kidney Development Small Business.

Date: February 18, 2005.

Time: 10 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: M. Chris Langub, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4112, MSC 7814, Bethesda, MD 20892, 301–496–8551, *langubm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Learning and Behavior in Children with Extremely Low Birthweight.

Date: February 18, 2005.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Karen Sirocco, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–0676, *siroccok@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Reviews in Bipolar Disorder.

Date: February 18, 2005.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Karen Sirocco, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–0676, *siroccok@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowship

Review: Sensory, Motor and Cognitive Neuroscience.

Date: February 23, 2005.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: John Bishop, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5180, MSC 7844, Bethesda, MD 20892, 301–435–1250, *bishopj@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group, Language and Communication Study Section.

Date: February 24–25, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria at Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Weijia Ni, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3190, MSC 7848, (for overnight mail use room # and 20817 zip), Bethesda, MD 20892, 301–435–1507, *niw@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowship Study Section.

Date: February 24–25, 2005.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Residence Inn, 7335 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Calbert A. Laing, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4210, MSC 7812, Bethesda, MD 20892, 301–435–1221, *laingc@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Neurotransporters, Receptors, and Calcium Signaling Study Section.

Date: February 24–25, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1111 30th Street, NW., Washington, DC 20007.

Contact Person: Peter B. Guthrie, Phd, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435–1239, *guthriep@csr.nih.gov.*

Name of Committee: Health of the Population Integrated Review Group, Health Services Organization and Delivery Study Section.

Date: February 24–25, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Kathy Salaita, Phd, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1014–2, MSC 7770, Bethesda, MD 20892, 301–451–8504, *salaitak@csr.nih.gov.*

Name of Committee: Cardiovascular Sciences Integrated Review Group, Myocardial Ischemia and Metabolism Study Section.

Date: February 24–25, 2005.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Inn, 1310 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Joyce C. Gibson, DSC, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, 301–435–4522, *gibsonj@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics C Study Section.

Date: February 24–25, 2005.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select, 480 King Street, Alexandria, VA 22314.

Contact Person: Barbara Whitmarsh, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301/ 435–4511, *whitmarshb@csr.nih.gov.*

Name of Committee: Oncological Sciences Integrated Review Group, Developmental Therapeutics Study Section.

Date: February 24–25, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Sheraton Suites, 801 North Saint Asaph Street, Alexandria, VA 22314.

Contact Person: Sharon K. Gubanich, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, (301) 435–1767, *gubanics@csr.nih.gov.*

Name of Committee: Endrocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Cellular, Molecular and Integrative Reproduction Study Section.

Date: February 24–25, 2005.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott (Pooks Hill), 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Dennis Leszczynski, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, (301) 435–1044, *leszczyd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, EMNR: Endrocrinology, Metabolism, Nutrition and Reproductive Sciences.

Date: February 24–25, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Krish Krishan, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435–1041, *krishnak@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Immunity and Host Defense Special Emphasis Panel.

Date: February 24–25, 2005.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Patrick K. Lai, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2215, MSC 7812, Bethesda, MD 20892, (301) 435–1052, *laip@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Vaccines Against Microbial Diseases.

Date: February 24–25, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate Hotel, 2650 Virginia Ave., NW., Washington, DC 20037.

Contact Person: Jian Wang, MD, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095D, MSC 7812, Bethesda, MD 20892, (301) 435–2778, *waingjia@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group, Cognition and Perception Study Section.

Date: February 24–25, 2005.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Barcello, 2121 P Street, NW., Washington, DC 20037.

Contact Person: Cheri Wiggs, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3180, MSC 7848, Bethesda, MD 20892, (301) 435–1261, *wiggsc@csr.nih.gov.*

Name of Committee: Health of the Population Integrated Review Group, Behavior Genetics and Epidemiology Study Section.

Date: February 24–25, 2005.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Yvette M. Davis, VMD, MPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, (301) 435–0906, *davisy@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Synthetic and Biological Chemistry B Study Section.

Date: February 24–25, 2005.
Time: 8:30 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.
Contact Person: Mike Radtke, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, (301) 435–1728, *radtkem@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Biochemistry and Biophysics of Membranes Study Section.
Date: February 24–25, 2005.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.
Contact Person: Gopa Rakhit, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435–1721, *rakhitg@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group, Social Psychology, Personality and Interpersonal Processes Study Section.
Date: February 24–25, 2005.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.
Contact Person: Anna L. Riley, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, (301) 435–2889, *rileyann@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group, Behavioral Medicine, Interventions and Outcomes Study Section.
Date: February 24–25, 2005.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Marriott Annapolis Waterfront, 80 Compromise Street, Annapolis, MD 21401.
Contact Person: Lee S. Mann, MA, JD, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, (301) 435–0677, *mannl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Clinical Neuroimmunology and Brain Tumors (CNBT).
Date: February 24–25, 2005.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Hilton Washington Embassy Row, 2015 Massachusetts Ave., NW., Washington, DC 20036.
Contact Person: Jay Joshi, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7846, Bethesda, MD 20892, (301) 435–1184, *joshij@csr.nih.gov.*

Name of Committee: Health of the Population Integrated Review Group, Social Sciences and Population Studies Study Section.
Date: February 24–25, 2005.
Time: 8:30 a.m. to 6:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.
Contact Person: Bob Weller, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3160, MSC 7770, Bethesda, MD 20892, (301) 435–0694, *wellerr@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Virology—A Study Section.
Date: February 24–25, 2005.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Select, 480 King Street, Old Towne Alexandria, VA 22314.
Contact Person: Joanna M. Pyper, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435–1151, *pyperj@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group, Adult Psychopathology and Disorders of Aging Study Section.
Date: February 24–25, 2005.
Time: 8:30 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.
Contact Person: Mariela Shirley, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, (301) 435–0913, *shirleym@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, SBIR: Early Childhood and Teen Risk Behaviors.
Date: February 24, 2005.
Time: 1 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Hotel Washington, Pennsylvania Ave at 15th Street, NW., Washington, DC 20004.
Contact Person: Claire E. Gutkin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7759, Bethesda, MD 20892, (301) 435–3139, *gutkincl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, SBIR\S 50R: Bioengineering Nanotechnology Initiative.
Date: February 24, 2005.
Time: 1 p.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Xiang-Ning Li, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Social Science and Population Studies R03s, R21s, and F32s.
Date: February 25, 2005.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: George Washington University Inn, 824 New Hampshire Ave., NW., Washington, DC 20037.
Contact Person: Valerie Durrant, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 435–3554, *durrantv@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, SBIR; Alcohol, Tobacco and Substance Abuse.
Date: February 25, 2005.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Hotel Washington, Pennsylvania Ave at 15th Street, NW., Washington, DC 20004.
Contact Person: Claire E. Gutkin, PhD, MPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7759, Bethesda, MD 20892, 301–594–3139, *gutkincl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Diagnosis, Course, and Outcome in Anxiety, Mood and Eating Disorders.
Date: February 25, 2005.
Time: 12 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.
Contact Person: Mariela Shirley, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301–435–0913, *shirleym@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 24, 2005.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–1681 Filed 1–28–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Commercializing Instruments, Reagents and Related Products Used for Template-Dependent Sequencing-by-Synthesis of Nucleic Acids at the Single Molecule Level, Wherein a Polymerase Carries the Donor Label

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the invention embodied in Patent Applications U.S. 60/151,580, filed August 29, 1999; PCT/US00/23736, filed August 29, 2000 and U.S. 10/070,053, filed June 10, 2002; entitled ''High Speed Parallel Molecular Nucleic Acid Sequencing'', to VisiGen Biotechnologies, Inc., having a place of business in Houston, Texas. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before April 1, 2005, will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Cristina Thalhammer-Reyero, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; e-mail: *ThalhamC@mail.nih.gov;* telephone: 301–435–4507; facsimile: 301–402–0220.

SUPPLEMENTARY INFORMATION: The invention relates to a method and apparatus for DNA and RNA sequencing, also known as Two Dye Sequencing (TDS). This invention is based on Fluorescence Resonance Energy Transfer (FRET), a technology increasingly in use for several molecular analysis purposes. In particular, the method consists of: (1) Attachment of engineered DNA polymerases labeled with a donor fluorophore to the surface (chamber) of a microscope field of view, (2) addition to the chamber of DNA with an annealed oligonucleotide primer, which is bound by the polymerase, (3) further addition of four nucleotide triphosphates, each labeled on the base with a different fluorescent acceptor dye, (4) excitation of the donor fluorophore with light of a wavelength specific for the donor but not for any of the acceptors, resulting in the transfer of the energy associated with the excited state of the donor to the acceptor fluorophore for a given nucleotide, which is then radiated via FRET, (5) identification of the nucleotides most recently incorporated into the complementary nucleic acid strand by recording the fluorescent spectrum of the individual dye molecules at specific locations in the microscope field, and (6) converting the sequential spectrum into a DNA sequence for each DNA molecule in the microscope field of view.

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 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, 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 404.7.

The field of use may be limited to ''Commercializing Instruments, Reagents and Related Products Used for Template-Dependent Sequencing-by-Synthesis of Nucleic Acids at the Single Molecule Level, wherein a Polymerase Carries the Donor Label.''

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: January 21, 2005.

Mark L. Rohrbaugh,

Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–1683 Filed 1–28–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Departmental Advisory Committee on Commercial Operations of Customs and Border Protection and Related Functions (COAC)

ACTION: Notice of meeting and announcement of membership.

SUMMARY: This notice announces the date, time, and location for the first meeting of the ninth term of the Departmental Advisory Committee on Commercial Operations of Customs and Border Protection and Related Functions (COAC) and the expected agenda for its consideration. It also announces the new members of the committee.

DATES: The next meeting of the COAC will be held on Tuesday, February 15, 2005, 9 a.m. to 1 p.m.

ADDRESSES: The meeting of the Departmental Advisory Committee on Commercial Operations of Customs and Border Protection and Related Functions (COAC) will be held in The Ronald Reagan International Trade Center Horizon Ballroom, 1300 Pennsylvania Avenue, NW., Washington, DC 20229 (phone 202–344–1440; fax 202–344–1969).

FOR FURTHER INFORMATION CONTACT: Ms. Monica Frazier, Office of the Assistant Secretary for Border and Transportation Security, Department of Homeland Security, Washington, DC 20528; telephone (202) 282–8431; facsimile (202) 282–8504.

SUPPLEMENTARY INFORMATION: The first meeting of the ninth term of Departmental Advisory Committee on Commercial Operations of Customs and Border Protection and Related Functions (COAC) will be held at the date, time and location specified above. This notice announces the expected agenda for its consideration and the new members of the committee. This meeting is open to the public; however, participation in COAC deliberations is limited to COAC members, Homeland Security and Treasury Department officials, and persons invited to attend the meeting for special presentations. Since seating is limited, all persons attending this meeting should provide notice by 2 p.m. e.s.t. on Wednesday, February 9, 2005, to Ms. Monica Frazier, Office of the Assistant Secretary for Border and Transportation Security, Department of Homeland Security, Washington, DC 20528; telephone (202) 282–8431; facsimile (202) 282–8504.

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 Ms. Monica Frazier, Office of the Assistant Secretary for Border and Transportation Security, Department of Homeland Security, Washington, DC 20528; telephone (202) 282–8431; facsimile (202) 282–8504, as soon as possible.

Draft Agenda: The COAC is expected to pursue the following agenda, which may be modified prior to the meeting:

1. MTSA Subcommittee.
2. Security Subcommittee.
   a. Advance Cargo Information.
   b. WCO Security.
   c. C–TPAT Process Review.
3. Automation Issues.
   a. ACE funding and development schedule.
   b. ACS downtime.
4. International Trade Data System (ITDS).
5. Creation of Infrastructure Subcommittee.
6. Bioterrorism Act.
7. Focused Assessment Program.

Membership: The twenty members for the ninth term of COAC are: Anthony Barone, Pfizer; Sandra M. Fallgatter, JC Penny Purchasing Corp.; Jonathan Gold, Retail Industry Leaders Assn.; D. Scott Johnson, Gap, Inc.; Chris Koch, World Shipping Council; Marian Ladner, Strasburger and Price; Bruce Leeds, Boeing; Mary Jo Muoio, Barthco International, Inc.; Karen Phillips, Canadian National; Peggy Rutledge, Hapag-Lloyd Container Line; Norman Schenk, United Parcel Service; Lisa Schimmelpfenning, Wal-Mart Stores; Robert Schueler, Jr., Delphi Corporation; Kevin M. Smith, General Motors Corp.; Curtis Spencer, IMS Worldwide; Katherine M. Terricciano, Philips Electronics N. America; Thomas G. Travis, Sandler, Travis & Rosenberg; Henry White, Institute of International Container Lessors; J Michael Zachary, Port of Tacoma; Federico Zúñiga, National Customs Brokers and Forwarders Association of America.

Dated: January 26, 2005.

C. Stewart Verdery, Jr.,

Assistant Secretary for Border and Transportation Security Policy and Planning.

[FR Doc. 05–1769 Filed 1–28–05; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–0002–2005]

Directorate of Science and Technology; Notice of Meeting of Homeland Security Science and Technology Advisory Committee

AGENCY: Office of the Under Secretary for Science and Technology, DHS.

ACTION: Notice.

SUMMARY: The Homeland Security Science and Technology Advisory Committee (HSSTAC) will meet in closed session.

DATES: February 23, 2005, and February 24, 2005.

ADDRESS: The offices of Booz Allen Hamilton, Virginia Square Plaza, 3811 Fairfax Drive, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Brenda Leckey, Homeland Security Science and Technology Advisory Committee, Department of Homeland Security, Directorate of Science and Technology, Washington, DC 20528; telephone 202–254–5041; e-mail *HSSTAC@dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Pub. L. 92–463, as amended (5 U.S.C. App.2 *et seq.*). The HSSTAC will meet for purposes of: (1) Conducting annual administrative sessions (ethics and security briefings); (2) receiving detailed briefings on future Department and Directorate priorities; (3) identifying special issues that HSSTAC should pursue in 2005; (4) identifying special challenges (and resulting responses by) as well as major changes or initiatives facing the Directorate and its operating units for the coming year; (5) receiving subcommittee updates; and (6) receiving briefings on activities, programs, and accomplishments of the Office of Research & Development, the Homeland Security Advanced Projects Research Agency, and the Office of Systems Engineering and Development. In accordance with section 10(d) of the Federal Advisory Committee Act, Pub. L. 92–463, as amended (5 U.S.C. App. 2 *et seq.*), the Under Secretary for Science and Technology has determined that this HSSTAC meeting will concern matters which, if prematurely disclosed, would significantly frustrate implementation of proposed agency actions. Moreover, the administrative portions of the meeting will relate solely to the internal personnel rules and practices of the agency. Accordingly, pursuant to 5 U.S.C. 552b(c)(2) and (9)(B), the meeting will be closed to the public.

Public Comments: You may submit comments, identified by DHS–0002–2005, by *one* of the following methods:

- EPA Federal Partner EDOCKET Web Site: *http://www.epa.gov/feddocket.* Follow instructions for submitting comments on the Web site.

The Department of Homeland Security has joined the Environmental Protection Agency (EPA) online public docket and comment system on its Partner Electronic Docket System (Partner EDOCKET). The Department of Homeland Security and its agencies (excluding the United States Coast Guard and Transportation Security Administration) will use the EPA Federal Partner EDOCKET system. The USCG and TSA (legacy Department of Transportation (DOT) agencies) will continue to use the DOT Docket Management System until full migration to the electronic rulemaking federal docket management system in 2005.

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *hsstac@dhs.gov.* Include DHS–0002–2005 in the subject line of the message.
- Fax: 202–254–6177.
- Mail: Homeland Security Science and Technology Advisory Committee, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.epa.gov/feddocket,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.epa.gov/feddocket.*

Dated: January 21, 2005.

Charles E. McQueary,

Under Secretary for Science and Technology.

[FR Doc. 05–1726 Filed 1–28–05; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–030–1610–DS]

Notice of Availability (NOA) of the Draft Environmental Impact Statement (DEIS) for the McGregor Range Resource Management Plan Amendment (RMPA) and Notice of Opening of Public Comment Period With Public Meetings

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: NOA of a DEIS for the McGregor Range RMPA, New Mexico.

SUMMARY: In accordance with Section 202 of the National Environmental Policy Act of 1969 (NEPA), the BLM announces the availability of the DEIS for the McGregor Range RMPA.

The DEIS documents the direct, indirect, and cumulative environmental impacts of four alternative management plans for BLM-administered withdrawn public lands within the McGregor Range. When completed, the RMPA will fulfill the obligations set forth by NEPA, the Federal Land Policy and

Management Act, and associated Federal regulations.

DATES: The McGregor Range DEIS and RMPA will be available for review for 90 calendar days from the date the Environmental Protection Agency (EPA) publishes its NOA in the **Federal Register**. The BLM can best utilize your comments and resource information submissions within the 90-day review period provided above. Formal hearings and open house meetings will be scheduled to provide the public additional opportunities to submit comments on the McGregor Range DEIS and RMPA.

All hearings or meetings and any other public involvement activities will be announced at least 15 days in advance through public notices, media news releases, New Mexico BLM Web site announcements, or mailings.

ADDRESSES: A copy of the DEIS/RMPA has been sent to affected Federal, State, and local government agencies and to interested parties. The document will be available electronically on the following Web site: *http://www.nm.blm.gov.* Copies of the DEIS/RMPA will be available for public inspection at the following locations: BLM New Mexico State Office, 1474 Rodeo Road, Santa Fe, NM 87505; BLM Las Cruces Field Office, 1800 Marquess, Las Cruces, NM 88005. The current RMPs/EISs, and all other documents relevant to this planning process, are available for public review at the Las Cruces Field Office at the above address.

Written comments may be mailed directly, or delivered to the BLM at: Draft McGregor Range RMPA/EIS, BLM Las Cruces Field Office, 1800 Marquess, Las Cruces, NM 88005. Comments may be electronically mailed to: *LCFO_RMP@nm.blm.gov.* Comments may be faxed to the BLM at: (505) 525–4412. Comments that are e-mailed or faxed must include ''Comments on Draft McGregor RMPA/EIS'' in the subject line. Interested parties may also provide written comments during the public open house meetings and hearings. The BLM will only accept comments on the Draft McGregor Range RMPA/EIS if they are submitted in one of the four ways described above. To be given consideration by the BLM all DEIS/RMPA comment submittals must include the commenter's name and street address.

Our practice is to make comments, including the names and street addresses of each respondent, available for public review at the BLM office listed above during business hours 7:45 a.m. to 4:30 p.m., Monday through Friday, except for Federal holidays. Your comments may be published as part of the EIS process. Individual respondents may request confidentiality. If you wish to withhold your name or street address, or both, from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comments. Such requests will be honored to the extent allowed by law. We will not consider anonymous comments. All submissions from organizations and businesses will be made available for public inspection in their entirety.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Phillips, RMPA Team Leader, at the BLM Las Cruces Field Office (see address above), telephone (505) 525–4377. Requests for information may be sent electronically to: *LCFO_RMP@nm.blm.gov* with ''Attention: McGregor RMPA Information Request'' in the subject line.

SUPPLEMENTARY INFORMATION: In 1990, the BLM approved the McGregor Range RMPA that established management direction for the BLM managed withdrawn public lands and resources administered by the BLM Las Cruces Field Office, New Mexico. The administrative area is located in southern Otero County, New Mexico, and includes approximately 606,233 acres of withdrawn public lands within McGregor Range, which is a military training range managed by Ft. Bliss, Texas. Within the McGregor Range, Ft. Bliss administers an additional 70,884 acres owned by the Department of Defense and 17,864 acres managed by the U.S. Forest Service. In 1999, the Military Lands Withdrawal Act (PL 106–65) reauthorized the withdrawn public lands within McGregor Range for use by the Secretary of the Army for military maneuvering, training, and equipment development and testing; training for aerial gunnery, rocketry, electronic warfare; and tactical maneuvering and air support associated with the Air Force Tactical Target Complex; and other defense-related purposes. The Military Lands Withdrawal Act also directed the Secretary of the Interior, after consultation with the Secretary of the Army, to develop a plan for the management of withdrawn public lands. The DEIS documents the direct, indirect, and cumulative environmental impacts of four alternative plans for BLM-administered withdrawn public lands within the McGregor Range. The DEIS describes the physical, biological, cultural, historic, and socioeconomic resources in and around the surrounding planning area. The focus for impact analysis was based on resource issues and concerns identified during scoping and public involvement activities and opportunities. Potential impacts of concern regarding possible management direction and planning decisions (not in priority order) are: development of energy resources and mineral-related issues; special management designations; resource accessibility; special status species management; recreation access and opportunity; and cultural resources management.

Four alternatives were analyzed in detail: The No-action Alternative represents the continuation of existing management plans, policies, and decisions as established in the 1990 McGregor Range RMPA. Alternative A represents a balance of resource use and conservation. Alternative B emphasizes resource use and production. Alternative C represents an emphasis of resource conservation, protection, and enhancement of natural and cultural resources. The BLM's preferred alternative is Alternative A.

Since the publication of the Notice of Intent (NOI) to prepare an RMPA and EIS in the **Federal Register** on May 15, 2001, open house meetings, scoping meetings, and mailings have been conducted to solicit public comments and input. The Las Cruces Field Office has been providing updates on the development of this RMPA to the Otero County Board of Commissioners and the New Mexico Resource Advisory Council. Tribal governments with interests in the McGregor Range area were also contacted. From the publication date of the NOI in the **Federal Register**, through September 30, 2004, the BLM solicited for and received approximately 42 written comments from interested parties. In addition, two public meetings were held to provide the public with an opportunity to acquire information about the RMPA process and its status, and to submit comments. These public meetings were held in Alamogordo, New Mexico, on June 20, 2001, and in Las Cruces, New Mexico, on June 21, 2001. The two meetings resulted in 47 oral comments from the public. All comments presented throughout the process have been considered. Background information and maps used in developing the DEIS and RMPA are available for public viewing at the Las Cruces Field Office at the above address.

Dated: November 23, 2004.

Linda S.C. Rundell,

New Mexico State Director.

[FR Doc. 05–1689 Filed 1–28–05; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–100–05–1310–DB]

Notice of Meeting of the Pinedale Anticline Working Group

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (1976) and the Federal Advisory Committee Act (1972), the U.S. Department of the Interior, Bureau of Land Management (BLM) Pinedale Anticline Working Group (PAWG) will meet in Pinedale, Wyoming, for a business meeting. Group meetings are open to the public.

DATES: The PAWG will meet March 2 and 3, 2005, from 9 a.m. until 5 p.m.

ADDRESSES: The meeting of the PAWG will be held in the Lovatt room of the Pinedale Library, 155 S. Tyler Ave., Pinedale, WY.

FOR FURTHER INFORMATION CONTACT: Carol Kruse, BLM/PAWG Liaison, Bureau of Land Management, Pinedale Field Office, 432 E. Mills St., PO Box 738, Pinedale, WY, 82941; 307–367–5352.

SUPPLEMENTARY INFORMATION: The Pinedale Anticline Working Group (PAWG) was authorized and established with release of the Record of Decision (ROD) for the Pinedale Anticline Oil and Gas Exploration and Development Project on July 27, 2000. The PAWG advises the BLM on the development and implementation of monitoring plans and adaptive management decisions as development of the Pinedale Anticline Natural Gas Field (PAPA) proceeds for the life of the field.

After the ROD was issued, Interior determined that a Federal Advisory Committees Act (FACA) charter was required for this group. The charter was signed by Secretary of the Interior, Gale Norton, on August 15, 2002, and renewed on August 13, 2004. An announcement of committee initiation and call for nominations was published in the **Federal Register** on February 21, 2003, (68 FR 8522). PAWG members were appointed by Secretary Norton on May 4, 2004.

The agenda for these meetings will include discussions and recommendations on proposed monitoring plans submitted by individual task groups. At a minimum, public comments will be heard prior to lunch and adjournment of the meeting each day.

Dated: January 17, 2004.

Priscilla E. Mecham,

Field Office Manager.

[FR Doc. 05–1673 Filed 1–28–05; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–027–1020–PI–020H; G–05–0052]

Notice To Cancel a Public Meeting, Steens Mountain Advisory Council

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Cancellation notice of public meeting for the Steens Mountain Advisory Council.

SUMMARY: The February 7 and 8, 2005, Steens Mountain Advisory Council Meeting, previously scheduled to be held at the Bureau of Land Management (BLM), Burns District Office, 28910 Highway 20 West, Hines, Oregon 97738, has been cancelled. The original **Federal Register** notice announcing the meeting was published Tuesday, December 14, 2004, page number 74535.

FOR FURTHER INFORMATION CONTACT: Additional information concerning the SMAC may be obtained from Rhonda Karges, Management Support Specialist, Burns District Office, 28910 Highway 20 West, Hines, Oregon, 97738, (541) 573–4400 or *Rhonda_Karges@or.blm.gov* or from the following Web site: *http://www.or.blm.gov/Steens.*

Dated: January 25, 2005.

Karla Bird,

Andrews Resource Area Field Manager.

[FR Doc. 05–1715 Filed 1–28–05; 8:45 am]

BILLING CODE 4310–AG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID 933–1430–ET; DK–G05–0001; ID–15248]

Public Land Order No. 7624; Revocation of Secretarial Order Dated October 22, 1920; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order revokes a Secretarial Order in its entirety as it affects 36,578.69 acres of land withdrawn for the Bureau of Reclamation's Minidoka Project, American Falls Reservoir. The land is located within the Fort Hall Indian Reservation and would return to the management and jurisdiction of the Bureau of Indian Affairs.

EFFECTIVE DATES: January 31, 2005.

FOR FURTHER INFORMATION CONTACT: Jackie Simmons, BLM Idaho State Office, 1387 South Vinnell Way, Boise, Idaho, 208–373–3867.

SUPPLEMENTARY INFORMATION: A copy of the original Secretarial Order dated October 22, 1920 describing the land involved is available at the BLM Idaho State Office at the address above.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

The Secretarial Order dated October 22, 1920, which withdrew 36,578.69 acres of land for the Bureau of Reclamation's Minidoka Project American Falls Reservoir, is hereby revoked in its entirety.

Dated: January 6, 2005.

Rebecca W. Watson,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 05–1690 Filed 1–28–05; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before January 8, 2005. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written

or faxed comments should be submitted by February 15, 2005.

Carol D. Shull,

Keeper of the National Register of Historic Places.

ARKANSAS

Conway County

Mellettown United Methodist Church, (Mixed Masonry Buildings of Silas Owens, Sr. MPS) 274 Mallett Town Rd., Mallet Town, 05000041.

Faulkner County

Church of Christ, (Mixed Masonry Buildings of Silas Owens, Sr. MPS) AR 310, Guy, 05000040.
Hooten, E.E., House, (Mixed Masonry Buildings of Silas Owens, Sr. MPS) 400 AR 25 N, Guy, 05000039.
Lee Service Station, (Mixed Masonry Buildings of Silas Owens, Sr. MPS) 28 South Broadway, Damascus, 05000044.
Merritt, S.D., House, (Mixed Masonry Buildings of Silas Owens, Sr. MPS) 45 AR 25 N, Greenbrier, 05000038.
Owens, Silas, Sr., House, (Mixed Masonry Buildings of Silas Owens, Sr. MPS) 157 Solomon Grove Rd., Twin Groves, 05000045.
Sellers House, (Mixed Masonry Buildings of Silas Owens, Sr. MPS) 89 Acklin Gap Rd., Conway, 05000042.
Spears House, (Mixed Masonry Buildings of Silas Owens, Sr. MPS) 1235 AR 65 N, Greenbrier, 05000043.

Washington County

Morton, Mack, Barn, 11516 Appleby Rd., Appleby, 05000047.

CALIFORNIA

Los Angeles County

Petitfils—Boos House, 545 Plymouth Blvd., Los Angeles, 05000049.
Storrier—Stearns Japanese Garden, 270 Arlington Dr., Pasadena, 05000050.
Textile Center Building, 315 E. Eighth St., Los Angeles, 05000048.

DISTRICT OF COLUMBIA

District of Columbia

Woodward and Lothrop Service Warehouse, 131 M St. NE., Washington, 05000046.

FLORIDA

Broward County

Hammerstein House, 1520 Polk St., Hollywood, 05000051.
Hollywood Garden Club, 2940 Hollywood Blvd., Hollywood, 05000052.

GEORGIA

Bibb County

League, Ellamae Ellis, House, 1790 Waverland Dr., Macon, 05000053.

MAINE

Cumberland County

Caswell Public Library (Former), (Maine Public Libraries MPS) 42 Main St., Harrison, 05000056.
Dyke Mountain Annex, 319 Dyke Mountain Rd., Sebago, 05000059.
Payson House at Thornhurst, 48 Thornhurst Rd., Falmouth, 05000057.

Kennebec County

Heald House, 19 West St., Waterville, 05000058.

Oxford County

Otisfield Town House (Former), 53 Bell Hill Rd., Otisfield, 05000055.

York County

Parsons—Piper—Lord—Roy Farm, 309 Cramm Rd., Parsonsfield, 05000054.

NORTH DAKOTA

Ward County

Our Savior's Scandinavian Lutheran Church, 1 mi. N of NM 50 and 0.25 mi. W of Ward Cty Hwy 1, Coulee, 05000060.

PENNSYLVANIA

Fayette County

Summit Hotel, 101 Skyline Dr., North Union, 05000062.

Northampton County

Bethlehem Silk Mill, 238 W. Goepp St., Bethlehem, 05000065.

Philadelphia County

Plaza Apartments, 1719–1725 N 33rd Sts., 3226–3228 Clifford St., Philadelphia, 05000063.
St. Anthony Hall House, 3637 Locust Walk, University of Pennsylvania, Philadelphia, 05000064.

PUERTO RICO

San Juan Municipality

Edificio Patio Espanol, 153 Cruz St., San Juan, 05000061.

WASHINGTON

Mason County

taba das, Address Restricted, Potlatch, 05000066.

[FR Doc. 05–1662 Filed 1–28–05; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Meeting of the Yakima River Basin Conservation Advisory Group, Yakima River Basin Water Enhancement Project, Yakima, WA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of meeting.

SUMMARY: As required by the Federal Advisory Committee Act, notice is hereby given that the Yakima River Basin Conservation Advisory Group, Yakima River Basin Water Enhancement Project, Yakima, Washington, established by the Secretary of the Interior, will hold a public meeting. The purpose of the Conservation Advisory Group is to provide technical advice and counsel to the Secretary of the Interior and Washington State on the structure, implementation, and oversight of the Yakima River Basin Water Conservation Program.

DATES: Wednesday, February 23, 2005, 9 a.m.–4 p.m.

ADDRESSES: Bureau of Reclamation Office, 1917 Marsh Road, Yakima, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. James Esget, Manager, Yakima River Basin Water Enhancement Project, 1917 Marsh Road, Yakima, Washington, 98901; 509–575–5848, extension 267.

SUPPLEMENTARY INFORMATION: The purpose of the meeting will be to review the staff reports requested at the last meeting and provide program oversite. This meeting is open to the public.

Dated: January 12, 2005.

James A. Esget,

Program Manager.

[FR Doc. 05–1714 Filed 1–28–05; 8:45 am]

BILLING CODE 4310–MN–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Summary of Decisions Granting in Whole or in Part Petitions for Modification

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice of affirmative decisions issued by the Administrators for Coal Mine Safety and Health and Metal and Nonmetal Mine Safety and Health on petitions for modification of the application of mandatory safety standards.

SUMMARY: Under section 101 of the Federal Mine Safety and Health Act of 1977, the Secretary of Labor (Secretary) may allow the modification of the application of a mandatory safety standard to a mine if the Secretary determines either that an alternate method exists at a specific mine that will guarantee no less protection for the miners affected than that provided by the standard, or that the application of the standard at a specific mine will result in a diminution of safety to the affected miners.

Final decisions on these petitions are based on the petitioner's statements, comments and information submitted by interested persons, and a field investigation of the conditions at the mine. MSHA, as designee of the

Secretary, has granted or partially granted the requests for modification listed below. In some instances, the decisions are conditioned upon compliance with stipulations stated in the decision. The term FR Notice appears in the list of affirmative decisions below. The term refers to the **Federal Register** volume and page where MSHA published a notice of the filing of the petition for modification.

FOR FURTHER INFORMATION CONTACT: Petitions and copies of the final decisions are available for examination by the public in the Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209. For further information contact Barbara Barron at 202–693–9447.

Dated at Arlington, Virginia, this 25th day of January 2005.

Rebecca J. Smith,

Deputy Director, Office of Standards, Regulations, and Variances.

Affirmative Decisions on Petitions for Modification

Docket No.: M–2004–015–C.
FR Notice: 69 FR 23540.
Petitioner: Oxbow Mining, Inc.
Regulation Affected: 30 CFR 75.1100–2(b).
Summary of Findings: Petitioner's proposal is to use an alternative method for installing water lines for the entire length of the belt conveyors in lieu of keeping water line charged with water at all times. The Elk Creek Mine belt entry portal sits at approximately 6300 feet elevation, and in winter weather conditions causes freezing in the existing water line in the conveyor entry. This is considered an acceptable alternative method for the Elk Creek Mine. MSHA grants the petition for modification for the North Mains belt conveyor from crosscut 11 outby for the Elk Creek Mine with conditions.

Docket No.: M–2004–016–C.
FR Notice: 69 FR 23540.
Petitioner: Dolet Hills Lignite Company.
Regulation Affected: 30 CFR 77.803.
Summary of Findings: Petitioner's proposal is to use an alternative method of compliance when raising or lowering the boom and mast at construction sites during initial Dragline assembly. This method would only be used during the boom and mast raising or lowering process. The machine will not be performing mining operations when raising or lowering the boom for construction and maintenance. This is considered an acceptable alternative method for the Dolet Hills Lignite Mine. MSHA grants the petition for modification for dragline boom or mast raising, lowering, assembling, disassembling, or during major repairs which require raising or lowering the dragline boom or mast by the on-board generators for the Dolet Hills Lignite Mine with conditions.

Docket No.: M–2004–019–C.
FR Notice: 69 FR 27955.
Petitioner: Oak Grove Resources, LLC.
Regulation Affected: 30 CFR 75.507.
Summary of Findings: Petitioner's proposal is to use high-voltage submersible pumps in boreholes in an area of the Oak Creek Mine where water has accumulated. The pumps will be equipped with probes to determine a high and low water level, and will consist of redundant electronic pressure transducers that are suitable for submersible pump control application. This is considered an acceptable alternative method for the Oak Grove Mine. MSHA grants the petition for modification for the use of three-phase, alternating current submersible pump(s) installed in return and bleeder entries and in sealed areas in the Oak Grove Mine with conditions.

Docket No.: M–2004–020–C.
FR Notice: 69 FR 30726.
Petitioner: D & D Anthracite Coal Company.
Regulation Affected: 30 CFR 75.335.
Summary of Findings: Petitioner's proposal is to use wooden materials of moderate size and weight for constructing seals due to the difficulty in accessing previously driven headings and breasts containing inaccessible abandoned workings; to accept a design criteria in the 10 psi range; and to permit the water trap to be installed in the gangway seal and sampling tube in the monkey seal for seals installed in pairs. This is considered an acceptable alternative method for the Primrose Slope Mine. MSHA grants the petition for modification for seals installed in the Primrose Slope Mine with conditions.

Docket No.: M–2004–024–C.
FR Notice: 69 FR 35686.
Petitioner: Consolidation Coal Company.
Regulation Affected: 30 CFR 75.364(b)(2).
Summary of Findings: Petitioner's proposal is to establish evaluation check points 1 and 2 to evaluate and confirm the proper ventilation between the Sugar Run Seals and the 3 North Bleeder Seals areas through the Main North headings, due to deteriorating rib and roof conditions which will expose personnel to hazardous conditions if the affected area is traveled in its entirety. This is considered an acceptable alternative method for the Loveridge No. 22 Mine. MSHA grants the petition for modification for the unsafe-to-travel segment (approximately 950 feet) of the Sugar Run Bottom area designated return entries used in ventilating between the Sugar Run Seals and the 3 North Bleeder Seals of the Loveridge No. 22 Mine with conditions.

Docket No.: M–2004–025–C.
FR Notice: 69 FR 43628.
Petitioner: Consolidation Coal Company.
Regulation Affected: 30 CFR 75.312(c) and (d).
Summary of Findings: Petitioner's proposal is to test automatic closing doors and the automatic fan signal device at least every 31 days without removing miners from the mine. The petitioner will install an alarm system on the fans. The alarm system will have a mechanical switch mounted to the fan housing and designed to activate a relay in the fan monitoring panel when the air reversal prevention door is in the closed position. The relay will activate a warning light near the door location, and an audible and visible alarm will be provided at a location where a responsible person is always on duty in the working sections and will have a two-way communication while miners are working underground. This is considered an acceptable alternative method for the Loveridge No. 22 Mine. MSHA grants the petition for modification for tests of (1) the automatic fan stoppage signal device and (2) the automatically closing airflow-reversal-prevention doors to be performed without shutting down the mine fan, and without removing the miners from the mine at the Loveridge No. 22 Mine with conditions.

Docket No.: M–2004–027–C.
FR Notice: 69 FR 43628.
Petitioner: Snyder Coal Company.
Regulation Affected: 30 CFR 49.2.
Summary of Findings: Petitioner's proposal is to use two mine rescue teams of three members with one alternate to serve both teams in lieu of two mine rescue teams with five members and one alternate. The petitioner asserts that to use five or more rescue team members in the confined working places of the mine would result in a diminution of safety to the miners and the rescue team. This is considered an acceptable alternative method for the No. 1 Rock Slope Mine. MSHA grants the petition for modification for the No. 1 Rock Slope Mine with conditions.

Docket No.: M–2004–031–C.
FR Notice: 69 FR 43628.
Petitioner: Eastern Associated Coal Corporation.

Regulation Affected: 30 CFR 75.507.

Summary of Findings: Petitioner's proposal is to use a 480-volt, three-phase alternating current electric power circuit for its non-permissible deep well submersible pump installed in the Shriver Shaft. This petition was filed for existing safety standard 30 CFR 75.364(b)(7). The applicable section of the regulation is 30 CFR 75.507, because item 4 of the special terms and conditions in a previous petition for modification, docket number M–86–35–C, granted November 17, 1986, and made final December 20, 1986, states ''Air passing through the tunnel shall not be used to ventilate non-permissible electric equipment or components.'' MSHA is requiring, for this 30 CFR 75.507 petition only, that the surface pump installations and control and power circuits(s) be examined under the 30 CFR 77.502 requirements because the circuit(s) that enter into the underground areas of the mine cannot be examined in their entirety to satisfy the requirements of 30 CFR 75.512 or the 30 CFR 75.364(b)(7) week examination requirement. This is considered an acceptable alternative method for the Federal No. 2 Mine. MSHA grants the petition for modification for the Federal No. 2 Mine with conditions.

Docket No.: M–2004–037–C.

FR Notice: 69 FR 55841.

Petitioner: Eastern Associated Coal Corporation.

Regulation Affected: 30 CFR 75.503.

Summary of Findings: Petitioner's proposal is to use trailing cables longer than the cable length specified in 30 CFR 18.35 for certain roof bolters, mobile roof supports, and shuttle cars. The cables for roof bolters will not exceed 900 feet, and 850 feet for shuttle cars. The cables for the 480-volt mobile roof supports will not be smaller than a No. 4 A.W.G., the trailing cables for roof bolters (e) will not be smaller than No. 2 A.W.G., and the cables for shuttle cars will not be smaller than No. 1/0. This is considered an acceptable alternative method for the Harris No. 1 Mine. MSHA grants the petition for modification for the Harris No. 1 Mine with conditions.

[FR Doc. 05–1694 Filed 1–28–05; 8:45 am]

BILLING CODE 4510–43–P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings of the Board of Directors and Four of the Board's Committees

TIMES AND DATES: The Legal Services Corporation Board of Directors and four of its Committees will meet February 4–5, 2005 in the order in which set forth in the following schedule.

Meeting Schedule

Friday, February 4, 2005

9 a.m.
1. Annual Performance Reviews Committee
2. Finance Committee
3. Provision for the Delivery of Legal Services Committee
4. Operations & Regulations Committee

Saturday, February 5, 2005

9:15 a.m.
1. Operations & Regulations Committee
2. Board of Directors

LOCATION: The Melrose Hotel, 2430 Pennsylvania Avenue, NW.

STATUS OF MEETINGS: Open, except as noted below.

- *Status:* February 4, 2005 Annual Performance Reviews Committee Meeting—Closed. The Performance Reviews Committee meeting will be closed to the public. The closing is authorized by the relevant provisions of the Government in the Sunshine Act [5 U.S.C. 552b(c)(2) and (6)] and the Legal Services Corporation's corresponding regulation 45 CFR 1622.5(a) and (e). A copy of the General Counsel's Certification that the closing is authorized by law will be available upon request.
- *Status:* February 5, 2005 Board of Directors Meeting—Open, except that a portion of the meeting of the Board of Directors may be closed pursuant to a vote of the Board of Directors to hold an executive session. At the closed session, the Corporation's General Counsel will report to the Board on litigation to which the Corporation is or may become a party, and the Board may act on the matters reported. The closing is authorized by 5 U.S.C. 552b(c)(2) and LSC's corresponding regulation 45 CFR 1622.5(a); 5 U.S.C. 552b(c)(6) and LSC's corresponding regulation 45 CFR 1622.5(e); 5 U.S.C. 552b(c)(7) and LSC's implementing regulation 45 CFR 1622.5(f)(4), and 5 U.S.C. 522b(c)(9)(B) and LSC's implementing regulation 45 CFR 1622.5(g); and 5 U.S.C. 552b(c)(10) and LSC's corresponding regulation 45 CFR 1622.5(h). A copy of the General Counsel's Certification that the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

Friday, February 4, 2005

Annual Performance Reviews Committee (February 4, 2004)

Closed Session

1. Approval of agenda
2. Approval of the minutes of the Executive Session of the Committee's meeting of November 19, 2004
3. Consider and act on internal procedures for annual performance evaluations of LSC President and Inspector General
4. Meet with Helaine Barnett
5. Consider and act on other business

Finance Committee

Open Session

1. Approval of agenda
2. Approval of the minutes of the Committee's meeting of November 20, 2004
3. Approval of the minutes of the Executive Session of the Committee's meeting of November 20, 2004
4. Presentation by Inspector General of the FY 2004 annual financial audit
5. Presentation of LSC's Financial Reports for the two-Month Period Ending November 30, 2004
6. Consider and act on the President's and Inspector General's recommendations for the FY 2005 Consolidated Operating Budget
7. Discussion of FY 2006 Budget Request
8. Review and act on a resolution to amend the LSC Flexible Benefits Plan
9. Report on Veterans Program
   - David Isbell, Chair of the Veterans Consortium Pro Bono Program
   - Chief Judge Ivers of the U.S. Court of Appeals for Veterans Claims
   - Bristow Hardin, OPP Staff
10. Public comment
11. Consider and act on other business
12. Consider and act on adjournment of meeting

Closed Session

13. Briefing [1] on OIG Budget

Committee on Provision for the Delivery of Legal Services

1. Approval of agenda

[1] Any portion of the closed session consisting solely of staff briefings does not fall within the Sunshine Act's definition of the term ''meeting'' and, therefore, the requirements of the Sunshine Act do not apply to any such portion of the closed session. 5 U.S.C. 552(b)(a)(2) and (b). See also 45 CFR 1622.2 and 1622.3.

2. Approval of the Committee's meeting minutes of November 19, 2004
3. Presentation on Mapping Project
• Introduction by Kirt West, Inspector General
• Report by David Maddox, OIG Staff
4. Presentation on Technology Initiative Grants
• Introduction by Michael Genz, Director, OPP
• Report by Joyce Raby and Glenn Rawdon, OPP Staff
5. Report on Mentoring Project
• Introduction by Helaine Barnett
• Report by members of the LSC Mentoring Committee
6. Public comment
7. Consider and act on other business
8. Consider and act on adjournment of meeting

Operations & Regulations Committee (February 4–5, 2005)

Open Session

1. Approval of agenda
2. Approval of the Committee's meeting minutes of November 19–20, 2004
3. Approval of the minutes of the Executive Sessions of the Committee's meetings of November 19–20, 2004
4. Consider and act on Notice of Proposed Rulemaking on Financial Eligibility, 45 CFR Part 1611
a. Staff report;
b. OIG's report; and
c. Public comment
5. Consider and act on Mr. Dean Andal's petition for rulemaking to amend LSC regulations on Class Actions, 45 CFR Part 1617
a. Staff report;
b. OIG's report; and
c. Public Comment
6. Briefing by OIG and OCE on Compliance Responsibilities

Closed Session

7. Briefing on Salaries and Benefits of LSC Employees
• Kirt West and Helaine Barnett
8. Inspector General's Briefing on the OIG's Review of the Lease for 3333 K Street

Open Session

9. Other public comment
10. Consider and act on other business
11. Consider and act on adjournment of meeting

Saturday, February 5, 2005

Operations & Regulations Committee (February 4–5, 2005)

Open Session

1. Approval of agenda
2. Approval of the Committee's meeting minutes of November 19–20, 2004
3. Approval of the minutes of the Executive Sessions of the Committee's meetings of November 19–20, 2004
4. Consider and act on Notice of Proposed Rulemaking on Financial Eligibility, 45 CFR Part 1611
d. Staff report;
e. OIG's report; and
f. Public comment
5. Consider and act on Mr. Dean Andal's petition for rulemaking to amend LSC regulations on Class Actions, 45 CFR Part 1617
b. Staff report;
b. OIG's report; and
c. Public Comment
6. Briefing by OIG and OCE on Compliance Responsibilities

Board of Directors Annual Meeting

Open Session

1. Consider and act on nominations for the Chairman of the Board of Directors
2. Consider and act on nominations for the Vice Chairman of the Board of Directors
3. Consider and act on delegation to Chairman of authority to make committee assignments
4. Approval of minutes of the Board's meeting of November 20, 2004
5. Approval of minutes of the Executive Session of the Board's meeting of November 20, 2004
6. Approval of minutes of the Executive Session of the Search Committee's meeting of July 19, 2004
7. Approval of minutes of the Executive Session of the Search Committee's meeting of August 12, 2004
8. Chairman's Report
9. Members' Reports
10. President's Report
11. Inspector General's Report
12. Consider and act on the report of the Committee on the Provision for the Delivery of Legal Services
13. Consider and act on the report of the Finance Committee
14. Consider and act on the report of the Operations & Regulations Committee
15. Consider and act on the report of the Annual Performance Reviews Committee
16. Consider and act on Board's meeting schedule for calendar year 2005
17. Report on LSC Pilot Loan Repayment Assistance Program (LRAP)
18. Consider and act on other business
19. Public comment
20. Consider and act on whether to authorize an executive session of the Board to address items listed below under Closed Session

Closed Session

21. Briefing by the Inspector General on the activities of the Office of Inspector General
22. Consider and act on General Counsel's report on potential and pending litigation involving LSC
23. Briefing on Board Travel Policies
24. Consider and act on motion to adjourn meeting

CONTACT PERSON FOR INFORMATION: Patricia D. Batie, Manager of Board Operations, at (202) 295–1500.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Patricia D. Batie, at (202) 295–1500.

Dated: January 27, 2005.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 05–1781 Filed 1–27–05; 10:37 am]

BILLING CODE 7050–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB Review: comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearaqnce under the Paperwork Reduction Act of 1995, Public Law 104–13. This is the second notice for public comment; the first was published in the **Federal Register** at 69 FR 62304, and no comments were received. NSF is forwarding the proposed renewal submission to the Office of Managaement and Budget (OMB) for clearance simultaneously with the publication of this second notice. Comments regarding (a) 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; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of