Type of respondent	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Totals	1,500			701

* These individuals are included in the 1,500 above.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information Contact: To request more information on the proposed project or obtain a copy of the data collection plans and instruments, contact Dr. Luigi Ferrucci, Principal Investigator, NIA Clinical Research Branch, Harbor Hospital, 5th Floor, 3001 S. Hanover, Baltimore, MD 21225, or call this non-toll-free number (410) 350–3936 or E-mail your request including your address to: *Ferruccilu@grc.nia.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: September 8, 2010.

Melissa Fraczkowski,

Project Clearance Liason, NIA, National Institutes of health.

[FR Doc. 2010–23263 Filed 9–16–10; 8:45 am]

BILLING CODE 4140–01–P

FEDERAL TRADE COMMISSION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1356–N]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Inspector General

Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws

AGENCY: Federal Trade Commission (FTC), Centers for Medicare & Medicaid Services (CMS), and Office of the Inspector General (OIG), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public workshop hosted by the Federal Trade Commission (FTC), the Centers for Medicare & Medicaid Services (CMS), and the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS). This workshop will include panel discussions and a listening session on certain legal issues related to Accountable Care Organizations (ACOs). Physicians, physician associations, hospitals, health systems, consumers, and all others interested in ACOs are invited to participate, in person or by calling into the teleconference. The meeting is open to the public, but attendance is limited to space and teleconference lines available. An agenda will be posted on the CMS Web site at *http://www.cms.gov/center/physician.asp* prior to the session.

DATES: *Meeting Date:* The public workshop will be held on Tuesday, October 5, 2010 from 9 a.m. until 4:30 p.m. Eastern Daylight Time (E.D.T.).

Deadline for Meeting Registration and Request for Special Accommodations: Registration opens on September 16, 2010. Registration must be completed by 5 p.m. e.d.t. on September 27, 2010. Requests for special accommodations must be received by 5 p.m. e.d.t. on September 27, 2010.

Deadline for Submission of Written Comments or Statements for Discussion at the Workshop: Written comments or statements to be considered for discussion at the Workshop may be sent via mail or electronically to the address specified in the **ADDRESSES** section of this notice and must be received by 5 p.m. E.D.T. on September 27, 2010.

ADDRESSES: *Meeting Location:* The public workshop will be held in the main auditorium of the Central Building of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Registration and Special Accommodations: Persons interested in attending the meeting in person must register by completing the on-line registration via the CMS Web site at *http://www.cms.hhs.gov/apps/events/event.asp?id=607* Individuals who require special accommodations should send an e-mail request to *thomas.carey@hhs.gov* or via regular mail to the address specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Information regarding attending via teleconference and Web conference will be posted on the CMS Web site at *http://www.cms.gov/center/physician.asp* prior to the session.

Written Comments or Statements: Written comments or statements may be sent via e-mail to *ACOlegalissues@cms.hhs.gov* or sent via regular mail to: Attn: ACO Legal Issues, Mail Stop C5–15–12, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

All persons planning to make a statement in person at the afternoon listening session are urged to submit statements in writing in advance of the listening session and should subsequently submit the information electronically by the timeframe specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Kristin Bohl at (410) 786–8680, for issues specific to CMS.

Elizabeth Jex at (202) 326–3273, for issues specific to FTC.

Patrice Drew at (202) 619–1368, for issues specific to OIG.

Thomas Carey at (410) 786–4560, for general and logistical issues. You may also send general and logistical inquiries about this workshop via e-

mail to *thomas.carey@hhs.gov* or via regular mail at Centers for Medicare & Medicaid Services, Mail Stop C5–15–12, 7500 Security Boulevard, Baltimore, MD 21244–1850.

SUPPLEMENTARY INFORMATION:

I. Background

The Affordable Care Act seeks to improve the quality of health care services and to lower health care costs by encouraging providers to create integrated health care delivery systems. These integrated systems will test new reimbursement methods intended to incentivize providers to enhance health care quality and lower costs. One important delivery system reform is the Affordable Care Act's Shared Savings Program, section 3022 of the Affordable Care Act, which promotes the formation and operation of Accountable Care Organizations (ACOs). Under this provision, "groups of providers . . . meeting the criteria specified by the Secretary may work together to manage and coordinate care for Medicare . . . beneficiaries through an [ACO]." An ACO may receive payments for shared savings if the ACO meets certain quality performance standards established by the Secretary. In addition, under section 3021 of the Affordable Care Act, the Secretary is authorized to test whether ACOs improve the quality of care for Medicare beneficiaries and reduce unnecessary costs for the Medicare program.

A variety of legal regimes—such as the antitrust laws, the physician self-referral prohibition (section 1877 of the Social Security Act (the Act)), the Federal anti-kickback statute (section 1128B(b) of the Act), and the civil monetary penalty (CMP) law (sections 1128A(b)(1) and (2) of the Act)—will apply to ACOs, including those participating in the Medicare Shared Savings Program pursuant to section 3022 of the Affordable Care Act. The Federal Trade Commission (FTC) together with the Department of Justice Antitrust Division enforce the Federal antitrust laws; the Centers for Medicare & Medicaid Services (CMS) has primary enforcement authority for the physician self-referral prohibition; and the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) enforces the anti-kickback statute and CMP law and imposes CMPs for knowing violations of the physician self-referral prohibition. Each of these agencies recognizes the importance of evaluating how to apply these laws to the creation and operation of ACOs. All of these laws also are relevant to the regulations that CMS is developing to implement the Medicare Shared Savings Program.

In addition, an ACO may wish to contract with payers in the private health care market, as well as with CMS. Experience has shown that integrating health care delivery among independent providers is a complex process that requires a substantial commitment of health care providers' resources and time.[1] Recent commentary suggests that, because of the resources and time required to integrate independent provider practices, health care providers are more likely to integrate their care delivery for Medicare and Medicaid beneficiaries if they also use the same delivery system for patients covered by health care insurance in the private market. The potential for ACOs to operate in both public and private insurance markets further supports the need to explore the application to ACOs of the laws discussed above for which the FTC, CMS, and OIG have enforcement responsibilities.

II. Workshop Format, Discussion Topics, and Solicitation of Public Comment

A. Format of Panel Discussions and Listening Session

To explore these issues, the FTC, CMS, and OIG will be hosting a public workshop on October 5, 2010 to obtain information from industry stakeholders who have an interest in, or experience with, the development and operation of ACOs. One key focus of the workshop will be to assess how the variety of possible ACO structures in different health care markets could affect the prices and the quality of health care delivered to privately insured consumers, as well as to Medicare and Medicaid beneficiaries. Another key focus will be whether and, if so, how the requirements of the laws discussed above could or should be addressed in the regulations that CMS is developing for the Medicare Shared Savings Program. Finally, the workshop will focus on whether and, if so, to what extent any safe harbors, exceptions, exemptions, or waivers from the laws discussed above may be warranted.

1. FTC Panel Discussions

The two morning sessions will be devoted to exploring antitrust issues through moderated panel discussions. Panelists for both antitrust panels will include health care providers with integration efforts planned and underway, payers (insurers, employers, and consumers), and experts in health care policy.

At the first session, the panelists will address circumstances under which collaboration among independent health care providers in an ACO (not including a merger), permits ACO providers to engage in joint price negotiations with private payers without running the risk of engaging in illegal price fixing under the antitrust laws. In particular, the panel will address the indicia of clinical integration sufficient to indicate that an ACO is likely to enable participating providers to improve the quality of their health care services and whether joint price negotiation is reasonably necessary to achieve these efficiencies. Such indicia could include, for example, the degree to which the providers engage in integrated activities, the information processes used to ensure that providers are coordinating patient care, incentives for providers to adhere to evidence-based care protocols such as financial risk sharing, and/or financial and resource investments made by providers. The panel also will address options for dealing with Medicare ACOs that fail to achieve CMS-required quality performance standards and that, therefore, might no longer be eligible for Medicare Shared Savings Program payments under section 3022 of the Affordable Care Act.

At the second morning session, the panelists will explore ways to encourage formation of multiple ACOs among otherwise independent providers so that competition among ACOs in any given geographic market will drive improved quality and affordability of health care. For example panelists will explore: (1) The analysis of arrangements where providers or facilities are exclusive, or non-exclusive, to an ACO; (2) the impact, if any, of risk-based contracting (for example, global payments and/or capitated rates) on market power assessments; (3) ways to assess whether formation of an ACO among independent providers may allow the ACO to increase price and reduce the quality of care; and (4) the financial, utilization, outcome, and patient experience data necessary to monitor and measure the impact of an ACO on prices and quality in the relevant markets.

2. CMS and OIG Panel Discussion and Listening Session

The afternoon will consist of two separate sessions regarding how ACOs will interact with the physician self-referral prohibition, the anti-kickback statute, and the CMP law in order to

[1] Stephen M. Shortell, Lawrence P. Casalino, Elliott Fisher, "Implementing Accountable Care Organizations," Policy Brief (May 2010), available at: *http://www.law.berkeley.edu/files/chefs/Implementing_ACOs_May_2010.pdf.*

better inform CMS and OIG (HHS Agencies) decision-making regarding the application of these laws to ACOs. The first session will be a moderated panel discussion of industry stakeholders, including representatives of providers, suppliers, and health policy experts who will focus on the discussion topics listed below.

During the second session, a listening session, there will be an opportunity for other attendees to provide brief comments on the same topics either in person or via the teleconference, as time permits. An agenda for the moderated panel discussions and the listening session will be released at a later time.

B. Discussion Topics and Solicitation of Public Comment

The FTC and the HHS Agencies are interested in comments addressing the intersection of these laws and the various business models envisioned for ACOs with both the antitrust laws and the fraud and abuse laws. The FTC and the HHS Agencies are interested in details from the public concerning the types of contractual and financial relationships under existing or planned ACOs that might trigger or implicate the antitrust laws, the physician self-referral prohibition and/or the anti-kickback statute (for example, compensation and ownership relationships), as well as payment arrangements that might implicate the CMP law (for example, gainsharing structures). In addition to obtaining information on the planned legal structures or business models of ACOs, the HHS Agencies seek comments addressing whether the public believes that the incentive payments or shared savings to ACOs, or the distribution of these payments to the physicians or other providers and suppliers in the ACO, would trigger or implicate the physician self-referral prohibition, the anti-kickback statute, and/or the CMP law. Much of the discussion to date has involved the integration of group practices, hospitals, and networks of physicians or other professionals into ACOs, and we are interested in how these types of arrangements might be constrained by these laws. We are asking the public to describe in detail any potential impediments, including an explanation as to how current physician self-referral prohibition exceptions or anti-kickback statute safe harbors might be inadequate to address the types of financial arrangements that will be created by ACOs. We are also interested in explanations about the extent to which these laws currently accommodate integration and ways in which existing exceptions and safe harbors might be tailored to further address integration.

1. Exercise of the Section 3022 Affordable Care Act Waiver Authority

Section 3022 of the Affordable Care Act gives the Secretary authority to waive such requirements of Title XVIII as well as sections 1128A and 1128B of the Act as may be necessary to carry out the provisions of section 3022 of the Affordable Care Act. The HHS Agencies are interested in hearing from the public whether a waiver, to the extent granted, should apply only to the incentive payments distributed to the ACOs and participating physicians (and other participating suppliers or ACO professionals), or whether it would be necessary to create a broader waiver that would also apply to other financial relationships created by ACOs that participate in the Medicare Shared Savings Program under section 3022 of the Affordable Care Act. If the public believes that a broader waiver is necessary, the HHS Agencies request that interested stakeholders provide support for this view. For example, if the public recommends a waiver that applies to all contractual service relationships between ACOs and ACO professionals, the HHS Agencies are interested to hear why this is necessary and what safeguards should be required as part of such a broad waiver.

2. Creation of New Stark Exception and Anti-Kickback Safe Harbor

An alternative to the use of the Secretary's waiver authority under section 3022 of the Affordable Care Act would be for the Secretary to use her authority under section 1877(b)(4) of the Act to create a new shared savings/incentive payment exception to the physician self-referral prohibition. Similarly, OIG could consider a new safe harbor under section 1128B(b)(3) of the Act. CMS has attempted to address this issue in prior proposed rulemaking under section 1877 of the Act, and the HHS Agencies are interested in the public's recommendations for how a meaningful exception and safe harbor for the incentive payments related to the newly created ACOs could be crafted. In particular, they are interested in how a physician self-referral exception could be designed given that any new exception under section 1877 of the Act must present no risk of program or patient abuse.

C. Content and Timeframe for Submission of Written Comments or Statements

Written comments or statements should not include any sensitive personal information, such as an individual's Social Security number; date of birth; driver's license number or other State identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records and other individually identifiable health information.

Written comments or statements will be accepted and considered for discussion at the meeting if they are received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice.

III. Registration Instructions

For security reasons, any persons wishing to attend this meeting must register by the date listed in the **DATES** section of this notice. Persons interested in attending the meeting in person must register by completing the on-line registration via the designated Web site at *http://www.cms.hhs.gov/apps/events/event.asp?id=607*. The on-line registration system will generate a confirmation page to indicate the completion of your registration. Please print this page as your registration receipt.

Individuals may also participate in the listening session by teleconference or webcast. Information regarding attending via teleconference and Web conference will be posted on the CMS Web site at *http://www.cms.gov/center/physician.asp* prior to the session.

An audio download and transcript of the listening session will be available 2 weeks after completion of the listening session through the CMS Web site Physician Center Spotlights at *http://www.cms.gov/center/physician.asp*.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. The on-site check-in for visitors will begin at 7:30 a.m. E.D.T. Please allow sufficient time to complete security checkpoints.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and

instructions will be issued after the vehicle inspection.

• Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 90 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 350 registrants.

Authority: Section 3022 of the Affordable Care Act.

Dated: September 13, 2010.

By Direction of the Commission.

Donald S. Clark,

Secretary, The Federal Trade Commission.

Dated: September 9, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 13, 2010.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2010–23340 Filed 9–16–10; 8:45 am]

BILLING CODE 6750–01–P; 4120–01–P; 4152–01–P

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. App.), 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: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Muscle and Exercise Physiology Study Section.

Date: October 12–13, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard Ingraham, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, *ingrahamrh@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Risk Prevention and Intervention Addictions: Overflow.

Date: October 14–15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1000 29th Street, NW., Washington, DC 20007.

Contact Person: Gabriel B. Fosu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435–3562, *fosug@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pathogens and Symbiotes.

Date: October 19–20, 2010.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Richard G Kostriken, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–402–4454, *kostrikr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Mechanisms and Circuits Underlying Arousal.

Date: October 19–20, 2010.

Time: 9 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kristin Kramer, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5205, MSC 7846, Bethesda, MD 20892, (301) 437–0911, *kramerkm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Toxicology.

Date: October 19, 2010.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rass M. Shayiq, PhD, Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR10–142: Interface of the Life and Physical Sciences.

Date: October 20–22, 2010.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Malgorzata Klosek, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435–2211, *klosekm@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Health Services Organization and Delivery Study Section.

Date: October 20–21, 2010.

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

Agenda: To review and evaluate grant applications.

Place: InterContinental Mark Hopkins Hotel, 999 California Street, San Francisco, CA 94108.

Contact Person: Kathy Salaita, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7770, Bethesda, MD 20892, 301–451–8504, *salaitak@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–08–062: Alzheimer's Disease Pilot Clinical Trials.

Date: October 22, 2010.

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: Estina E Thompson, PhD, MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301–496–5749, *thompsone@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Biomedical Technology Research Resource.

Date: October 24–26, 2010.

Time: 7 p.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hill Hotel, 25 Charles Street, Boston, MA 02114.

Contact Person: Lee Rosen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171, *rosenl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer and Musculoskeletal Imaging Applications.

Date: October 25, 2010.

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