PICOTS (Population, Interventions, Comparators, Outcomes, Timing, Setting)

Populations

I. Adult and pediatric patients with an acute RTI and no clear indication for antibiotic treatment. Respiratory tract infections of interest include: acute bronchitis; otitis media; sore throat/pharyngitis/tonsillitis; rhinitis; sinusitis; cough and common cold.

II. Parents of pediatric patients with acute RTI and no clear indication for antibiotic treatment.

III. Healthy adults and/or children without a current acute RTI, who may develop an acute RTI in the future.

IV. Clinicians and others who care for patients with acute RTI in outpatient settings.

V. Groups whose attendance policies may indirectly affect the use of antibiotics, such as employers or school officials.

Interventions

Any strategy for improving appropriate use of antibiotics when not indicated for acute RTI, which may fall into various categories, including:

I. Educational, behavioral and psychological interventions that target clinicians, patients, or both.

II. Strategies to improve communication between clinicians and patients, such as those designed to improve shared decision making.

III. Clinical strategies, such as delayed prescribing of antibiotics, clinical prediction rules, use of risk assessment or diagnostic prediction, use of non-antibiotic alternatives, or use of relevant point-of-care (POC) diagnostic tests.

A. EPC will include any POC test that is available and used in primary care settings for diagnostic purposes with the ability to provide results within a reasonable period (e.g. during the clinic visit). Examples include inflammatory tests (e.g., procalcitonin, c-reactive protein [CRP], white blood cell, etc.), rapid multiplex polymerase chain reaction (PCR) tests used to rule in/out organisms (e.g. rapid strep test, influenza, RSV), routine diagnostic tests, such as chest x-ray, pulse oximetry, and blood gasses, when they are specifically evaluated as an intervention for improving antibiotic use.

IV. System level strategies, such as clinician reminders (paper-based or electronic), clinician audit and feedback, financial or regulatory incentives for clinicians or patients, antimicrobial stewardship programs, pharmacist review.

V. Multifaceted approaches that include numerous elements of one or more of the above strategies.

Comparators

I. Different strategies for improving appropriate use of antibiotics when not indicated for acute RTI.

II. Standard care without a strategy for improving appropriate use of antibiotics.

Outcomes

Key Question 1

- Increased appropriate prescription of antibiotics (primary outcome)
- Increased appropriate use of antibiotics (primary outcome)

Note: Studies may vary in how appropriateness is defined or determined. We will accept and record any definition of appropriateness. We will group together studies that use similar definitions of appropriateness and categorize the different groups based on concordance with (e.g., high, medium, low) select clinical practice guidelines (e.g., AAP, ACCP, AAFP). We will then evaluate whether the comparative effectiveness of strategies differ across categories. We may also find that overall reduction in antibiotic prescription or use is reported, without a determination of appropriateness. While this is not a direct measure of the primary outcomes, we will report these as indirect measures of the impact of the intervention.

Key Question 2

- Mortality
- Antibiotic resistance
- Medical complications
- Adverse drug effects, including clostridium difficile infections

Key Question 3

- Admission to hospital
- Clinic visits (Index, return and subsequent episodes), ED visits
- Time to return to work and/or school
- Patient satisfaction
- Quality of life
- Improvement in patient symptoms, speed of improvement
- Use of non-antibiotic treatments, such as over-the-counter medications
- Utilization of vaccinations
- Quality metrics

Key Question 4

Intermediate outcomes, such as improved knowledge regarding use of antibiotics for acute RTI (clinician and/or patient), or improved shared decision making

Key Question 5

Adverse effects of the strategy, such as increased time burden on clinicians, sustainability of intervention (e.g. measures of continued effectiveness over time), diagnostic resource use associated with POC testing, diagnostic coding (e.g. ICD billing codes) according to desired action (prescribe/not prescribe)

Timing

Any duration of follow-up.

Setting

I. Outpatient care settings including institutional settings
II. Emergency care settings
III. Other settings, such as school or workplace

Study Design

We will prioritize comparative studies with concurrent control groups (e.g. randomized controlled trial, prospective and retrospective cohort studies including database studies). For areas in which direct comparative evidence is lacking, we will include before-after studies, with or without a control group and with or without repeated measures.

Dated: June 16 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–14962 Filed 6–26–14; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10526, CMS–2540–10, CMS–265–11, CMS–10106 and CMS–R–235]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed

information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *August 26, 2014.*

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number_____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10526 Cost Sharing Reduction Reconciliation

CMS–2540–10 Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report

CMS–265–11 Independent Renal Dialysis Facility Cost Report and Supporting Regulations

CMS–10106 Medicare Authorization to Disclose Personal Health Information

CMS–R–235 Data Use Agreement (DUA) for Data Acquired from the Centers for Medicare & Medicaid Services (CMS)

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Cost Sharing Reduction Reconciliation; *Use:* Under established Department of Health and Human Services (HHS) regulations, qualified health plan (QHP) issuers will receive estimated advance payments of cost-sharing reductions throughout the year. Each issuer will then be subject to a reconciliation process at the end of the benefit year to ensure that HHS reimburses each issuer only for actual cost sharing. This information collection establishes the data elements that a QHP issuer would be required to report to HHS in order to establish the cost-sharing reductions provided on behalf of enrollees for the benefit year.

Form Number: CMS–10526 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 295; *Total Annual Responses:* 4,000,000; *Total Annual Hours:* 2,469. (For policy questions regarding this collection contact Patricia Meisol at 410–786–1917.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. Form CMS–2540–10 is used by Skilled Nursing Facilities (SNFs) and Skilled Nursing Facility Complexes participating in the Medicare program to report health care costs to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries.

Form Number: CMS–2540–10 (OMB control number: 0938–0463); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 14,185; *Total Annual Responses:* 14,185; *Total Annual Hours:* 2,865,370. (For policy questions regarding this collection contact Amelia Citerone at 410–786–3901.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Independent Renal Dialysis Facility Cost Report and Supporting Regulations; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS–265–11 cost report is needed to determine a provider's reasonable costs incurred in furnishing medical services to Medicare beneficiaries.

Form Number: CMS–265–11 (OMB control number: 0938–0263); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 5,677; *Total Annual Responses:* 5,677; *Total Annual Hours:* 369,005. (For policy questions regarding this collection contact Gail Duncan at 410–786–7278.)

4. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare Authorization to Disclose Personal Health Information; *Use:* Unless permitted or required by law, the

Health Insurance Portability and Accountability Act (HIPAA) prohibits Medicare (a HIPAA covered entity) from disclosing an individual's protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. Form CMS–10106, the Medicare Authorization to Disclose Personal Health Information, will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. *Form Number:* CMS–10106 (OMB control number: 0938–0930); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,298,329; *Total Annual Responses:* 1,298,329; *Total Annual Hours:* 324,582. (For policy questions regarding this collection contact Sam Jenkins at 410–786–3261.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Use Agreement (DUA) for Data Acquired from the Centers for Medicare & Medicaid Services (CMS); *Use:* The Privacy Act of 1974 allows for discretionary releases of data maintained in Privacy Act protected systems of records under § 552a(b) (Conditions of Disclosure). The mandate to account for disclosures of data under the Privacy Act is found at § 552a(c)(Accounting of Certain Disclosures). This section states that certain information must be maintained regarding disclosures made by each agency. This information is: Date, Nature, Purpose, and Name/Address of Recipient. Section 552a(e) sets the overall requirements that each agency must meet in order to maintain records under the Privacy Act. The Data Use Agreement (DUA) form is needed as part of the review of each CMS data request to ensure compliance with the requirements of the Privacy Act for disclosures that contain personally identifiable information (PII). The DUA form also provides data requestors and custodians with a formal means to agree to the data protection and destruction statutory and regulatory requirements of CMS' PII data. The Health Insurance Portability and Accountability Act (HIPAA) of 1996, § 1173(d) (Security Standards for Health Information) requires us to protect PII. Additionally, the Federal Information Security Management Act (FISMA) of 2002, § 3544 (b) (Federal Agency Responsibilities—Agency Program) also requires us to develop policies and procedures for the protection and destruction of sensitive data to include PII. We use the information collected by the DUA to track disclosures, conditions for disclosure, accounting of disclosures and agency requirements dictated by the Privacy Act, HIPAA and FISMA.

Form Number: CMS–R–235 (OMB control number: 0938–0734); *Frequency:* Annually; *Affected Public:* Private sector—business or other for-profits and not-for-profit institutions; *Number of Respondents:* 9,220; *Total Annual Responses:* 9,220; *Total Annual Hours:* 2,740. (For policy questions regarding this collection contact Sharon Kavanagh at 410–786–5441.)

Dated: June 24, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–15075 Filed 6–26–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–370 and CMS–377, CMS 437, CMS–10510, CMS–216–94, CMS–10494, CMS–10224, CMS–10472 and CMS–10499]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *July 28, 2014.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 or, Email: *OIRA_submission@omb.eop.gov*. To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment: