

III. How does the comparative effectiveness of treatment vary by patient characteristics, including age, sex, risk factors, comorbidities, characteristics of disease, anatomic segment affected, and characteristics of the therapy (e.g., exercise intensity, type of mechanical compression)?

IV. What are the comparative safety concerns associated with each treatment strategy (e.g., adverse drug reactions, bleeding)? Do the safety concerns vary by patient subgroup (age, sex, race, risk factors, comorbidities, anatomic segment, or disease severity)?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

KQ 1: Diagnosis

I. Population(s):

A. Adults (over age 18) with the diagnosis of LE varicose veins, LE chronic venous insufficiency/incompetence/reflux, and/or LE chronic venous thrombosis/obstruction (including post-thrombotic syndrome)

II. Diagnostic Measures:

A. Air plethysmography, LE venous duplex ultrasonography (with and without compression), invasive venography, magnetic resonance venography, computed tomographic venography, serum D-dimer testing, Villalta score

III. Comparators:

A. Diagnostic modalities listed above (air plethysmography, LE duplex venous ultrasonography [with and without compression], invasive venography, magnetic resonance venography, computed tomographic venography, serum D-dimer testing, Villalta score) will be compared to one another

IV. Outcomes:

A. Sensitivity, specificity, positive predictive value, negative predictive value, inter-rater reliability, internal consistency, test-retest reliability, false positives, false negatives, and positive and negative likelihood ratios for each diagnostic measure listed above will be compared

V. Timing:

A. Not applicable

VI. Settings:

A. All clinical settings, including inpatient and outpatient

KQs 2–3: Treatment

I. Population(s):

A. KQ 2: A symptomatic or symptomatic adults (over age 18) with the diagnosis of LE varicose veins and/or LE chronic venous insufficiency/incompetence/reflux:

i. Subgroup analysis: age, race/ethnicity, sex, body weight, CEAP classification, VCSS classification, severity of disease, anatomic segment affected (e.g., iliofemoral, infrainguinal), known malignancy, presence of LE ulcer

A. KQ 3: A symptomatic or symptomatic adults(over age 18) with the diagnosis of LE chronic venous thrombosis/obstruction (including post-thrombotic syndrome):

i. Subgroup analysis: age, race/ethnicity, sex, body weight, CEAP classification, VCSS classification, Villalta score, severity of disease, anatomic segment affected (e.g., iliofemoral, infrainguinal), known malignancy, presence of LE ulcer

II. Interventions:

A. KQ 2: lifestyle interventions (e.g., smoking cessation, leg elevation, weight reduction, exercise), medical therapy, local skin care/wound care, mechanical compression therapy, and invasive procedures (i.e., surgical and endovascular procedures)

i. Medical therapies: diuretics, aspirin, pentoxifylline, prostacyclins, zinc sulfate
ii. Invasive surgical/endovascular procedures: sclerotherapy (liquid, foam, glue), radiofrequency ablation, thermal ablation, chemical ablation, ambulatory phlebectomy, transilluminated powered phlebectomy, venous ligation, venous excision

B. KQ 3: lifestyle interventions (e.g., smoking cessation, leg elevation, weight reduction, exercise), medical therapy, local skin care/wound care, mechanical compression therapy, and invasive procedures (i.e., surgical and endovascular procedures)

i. Medical therapies: anticoagulants including warfarin, apixaban, rivaroxaban, edoxaban, and dabigatran; diuretics
ii. Invasive surgical/endovascular procedures: endovenous angioplasty/stenting, ultrasound accelerated thrombolysis for chronic DVT (EkoSonic® endovascular system), surgical thromboembolectomy

III. Comparators:

A. Specific treatments will be compared to other included treatments as described above or to no treatment (placebo or usual care)

IV. Outcomes:

A. Changes on standardized symptom scores (Villalta score, CEAP classification, AVVQ score, and VCSS score); qualitative reduction

in Ledema; qualitative reduction in LE pain; improvement in LE venous hemodynamics/reflux severity as measured by air plethysmography, duplex ultrasonography, or invasive venography; venous wound healing, recurrent ulceration, patient-reported quality of life (including AVVQ), repeat intervention, LE amputation E

B. Adverse effects of treatment, including: adverse drug reactions; bleeding (including intracranial bleeding); venous wound infection; contrast nephropathy; radiation-related injuries; exercise-related harms; periprocedural complications (vessel dissection, vessel perforation, and AV fistula), thrombophlebitis, venous thrombosis (including stent thrombosis), venous thromboembolic events (including PE), and death

V. Timing:

A. Studies with all durations of followup will be included in the review; for symptomatic patients, we will attempt to categorize studies into those that evaluate short-term (≤ 30 days), intermediate-term (31 days to 6 months), and long-term (≥ 6 months) events.

VI. Settings:

A. Any

Sharon B. Arnold,
Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: “*Survey of Hospital Quality Leaders.*” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on February 10, 2016 and

allowed 60 days for public comment. AHRQ received no substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by July 11, 2016.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Survey of Hospital Quality Leaders

The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospital Survey (HCAHPS) was first implemented on a voluntary basis in 2006 to assess patients' experiences with care. Today, hospitals subject to the Inpatient Prospective Payment System (IPPS) annual payment update provisions are required to collect and submit HCAHPS data in order to receive their full annual payment update. In addition, HCAHPS performance was added to the calculation of the value-based incentive payment in the Hospital Value-Based Purchasing (Hospital VBP) program, beginning with discharges in October 2012. The FY 2015 Hospital VBP program links 30% of the Inpatient Prospective Payment System hospitals' payment from CMS to HCAHPS performance.

Despite the high stakes associated with HCAHPS scores, little is known about the ways in which hospitals are using HCAHPS data and supplemental information about patient experience to understand and improve their patients' experiences.

This research has the following goals:

(1) To characterize the role of HCAHPS in hospitals' efforts to improve patient experiences

(2) to identify the types of quality improvement activities that hospitals implement to improve their HCAHPS scores

(3) to describe hospitals' perspectives on HCAHPS

(4) to determine the types of information collected by hospitals beyond those required for Hospital VBP

This study is being conducted by AHRQ through its contractor, the RAND Corporation, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

Survey of Hospital Quality Leaders: this survey will elicit information from approximately 500 hospital quality leaders in a variety of hospital settings, including high- and low-performing hospitals, facilities of varying sizes, and hospitals representing all nine geographic Census divisions. Hospital quality leaders will be asked to provide information about the use of HCAHPS in their hospital, with questions

addressing all of the substantive areas identified in the goals section above.

Characterizing hospitals' use of HCAHPS data will provide important insight into the activities hospitals conduct to improve patient experience scores. This information may be useful in supporting hospitals who lag behind their peers, learning from hospitals with outstanding records of patient experience, and providing recommendations that may be used to refine HCAHPS survey content.

Estimated Annual Respondent Burden

Table 1 shows the estimated annualized burden and cost for the respondents' time to participate in this data collection. These burden estimates are based on tests of data collection conducted on nine or fewer entities. As indicated below, the annual total burden hours are estimated to be 294 hours. The annual total cost associated with the annual total burden hours is estimated to be \$14,708.

Table 1 shows the estimated annualized burden for the respondents' time to participate in this data collection. The Survey of Hospital Quality Leaders will be administered to 500 individuals. Prior work suggests that 3-5 items can typically be completed per minute, depending on item complexity and respondent characteristics, (Hays & Reeve, 2010; Berry, 2009). We have calculated our burden estimate using a conservative estimate of 4.5 items per minute. The survey contains 159 items and is thus estimated to require an average administration time of 35 minutes. As indicated below, the annual total burden hours are estimated to be 294 hours.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS AND COST

| Collection task | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours | Average hourly wage rate* | Total cost burden |
|--|-----------------------|------------------------------------|--------------------|--------------------|---------------------------|-------------------|
| Survey of Hospital Quality Leaders | 500 | 1 | .59 | 294 | \$49.96 | \$14,708 |
| Totals | | | | 294 | | 14,708 |

* Based upon mean hourly wages, "National Compensation Survey: All United States December 2009—January 2011," U.S. Department of Labor, Bureau of Labor Statistics.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including

whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of

automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All

comments will become a matter of public record.

Sharon B. Arnold,
Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6069-N]

Medicare Program; Pre-Claim Review Demonstration for Home Health Services

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

ACTION: Notice.

SUMMARY: This notice announces a 3-year Medicare pre-claim review demonstration for home health services in the states of Illinois, Florida, Texas, Michigan, and Massachusetts where there have been high incidences of fraud and improper payments for these services.

DATES: This demonstration will begin in Illinois no earlier than August 1, 2016, in Florida no earlier than October 1, 2016, and in Texas no earlier than December 1, 2016. The demonstration will begin in Michigan and Massachusetts no earlier than January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Jennifer McMullen, (410) 786-7635.

Questions regarding the Medicare Pre-Claim Review Demonstration for Home Health Services should be sent to HHPreClaimDemo@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes the Secretary to develop demonstration projects that “develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act” (the Act). According to this authority, we will implement a Medicare demonstration that establishes a pre-claim review process for home health agencies (HHAs) to assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among HHAs providing services to

Medicare beneficiaries. The proposed demonstration will begin in Illinois not earlier than August 1, 2016, will begin in Florida not earlier than October 1, 2016, and will begin in Texas not earlier than December 1, 2016. The demonstration will begin in Michigan and Massachusetts not earlier than January 1, 2017. Providers in each state will be notified by the appropriate Medicare Administrative Contractor prior to the start of the demonstration in the state. Additionally, CMS will utilize other educational efforts to announce the program to stakeholders.

This demonstration will evaluate an additional method that may assist with the investigation and prosecution of fraud in order to protect the Medicare Trust Funds from fraudulent actions and improper payments. We believe this demonstration will bolster the efforts that CMS and its partners have taken in implementing a series of anti-fraud initiatives in these states and will provide valuable data that CMS working with its law enforcement partners, can use to combat the submission of fraudulent claims to the Medicare program. One such anti-fraud initiative is the use of temporary moratoria on the enrollment of new home health providers that were put in place in the Miami and Chicago that and were subsequently expanded to the Fort Lauderdale, Detroit, Dallas, and Houston metropolitan areas. These temporary moratoria prohibit the new enrollment of home health providers to help CMS prevent and combat fraud, waste, and abuse in these locations.

We also believe the data collected from this demonstration will assist with a second initiative, the Health Care Fraud Prevention and Enforcement Action Team (HEAT) Task Force, created by the Department of Health and Human Services and the Department of Justice (DOJ), and the Heat Task Force’s ongoing fight against Medicare fraud. The HEAT Task Force uses resources across the government to help prevent and stop fraud, waste, and abuse in the Medicare and Medicaid programs. Since 2007, the HEAT Task Force of the DOJ has charged more than 2,300 defendants with defrauding Medicare of more than \$7 billion and convicted approximately 1,800 defendants of felony health care fraud offenses. In addition, the data resulting from this demonstration could provide investigators and law enforcement with important information to determine how to focus their investigation activities to identify and combat home health fraud, and in so doing, protect the Medicare Trust Funds from fraudulent actions and improper payments.

This demonstration may also help prevent improper payments in geographic areas where HHA providers are known to have a high incidence of fraud. The improper payment rate for HHA claims has been increasing over the past several years, and fraud is one factor contributing to the increase. It is important to note that while all payments made as a result of fraud are considered “improper payments,” not all improper payments constitute fraud. CMS’ Comprehensive Error Rate Testing (CERT) program, which measures Medicare’s improper payment rate, estimates the payments that did not meet Medicare coverage, coding, and billing rules. The fiscal year (FY) 2015 Department of Health and Human Services Agency Financial Report reported that the CERT program’s calculated 2015 improper payment rate for HHA claims increased to 59.0 percent from the 2014 rate of 51.4 percent and the 2013 rate of 17.3 percent. The increase in the 2015 improper payment rate was primarily due to “insufficient documentation” errors, specifically, insufficient documentation to support the medical necessity of the services. Similar documentation errors have also occurred in previous years. For example, the 2014 CERT report found that the majority of home health payment errors occurred when the narrative portion of the face-to-face encounter documentation did not sufficiently describe how the clinical findings from the encounter supported the beneficiary’s homebound status and need for skilled services.

Due to the substantial increase in improper payments and concerns raised by the home health industry, relating to implementation of the face-to-face encounter documentation requirement, we made Medicare HHA payment policy changes in an effort to simplify the face-to-face encounter regulations. Specifically, as of January 1, 2015, a separate narrative is no longer required as part of the face-to-face documentation. Rather, the certifying physician’s or the acute/post-acute care facility’s medical record(s) for the patient must contain sufficient documentation to substantiate eligibility for home health services.

Despite these recent changes, we continue to see cases in which the medical record does not support eligibility for the home health benefit, which constitute “insufficient documentation” errors. Moreover, we note that the recent regulatory changes do not address HHA errors in home health billing other than those related to the face-to-face narrative requirement.