

to provide information to enable the Board to carry out the provisions of the subsection (15 U.S.C. 1693o-2(a)(3)(B)). The obligation of issuers to respond to the issuer survey is mandatory. The Board generally regards the information collected from each individual issuer on the FR 3063a survey as confidential commercial and financial information, which is protected by exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)). The Board, however, may publicly release aggregate or summary information in a way that does not reveal the individual issuer.

Board of Governors of the Federal Reserve System, November 16, 2020.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2020-25582 Filed 11-18-20; 8:45 am]

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FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than December 4, 2020.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org.

1. *Jeremy Francis Gilpin, South Lake Tahoe, California, and Jeffrey Alan Smith, Atlanta, Georgia, as a group acting in concert*; to acquire voting shares of Community Bankshares, Inc., and thereby indirectly acquire voting shares of Community Bank and Trust—West Georgia, both of LaGrange, Georgia.

B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Elizabeth L. Morgan, Austin, Texas, as trust protector of fifteen trusts associated with Mr. James W. Collins, McAllen, Texas*; to acquire control of voting shares of VBT Financial Corporation, and thereby indirectly acquire control of voting shares of Vantage Bank Texas, both of San Antonio, Texas.

Board of Governors of the Federal Reserve System, November 16, 2020.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Integrated Pain Management Programs

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Integrated Pain Management Programs*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: Submission Deadline on or before December 21, 2020.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Jenae Benns, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Integrated Pain Management Programs*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Integrated Pain Management Programs*, including those that describe adverse events. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/integrated-pain-management/protocol>.

This is to notify the public that the EPC Program would find the following information on *Integrated Pain Management Programs* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov* trial number.

- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion

criteria, and primary and secondary outcomes.

■ Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ’s EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <https://>

www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

KQ1: What are the effectiveness and harms of integrated or comprehensive pain management programs for Medicare beneficiaries with complex acute/subacute pain or chronic, non-active cancer pain? Population subgroups of interest include those with disabilities (including ESRD), prior substance use disorder, psychological co-morbidities (including suicidal behaviors), and degree of nociplasticity.

KQ2: Have any of the following factors been evaluated and/or shown to impact outcomes in studies of comprehensive or integrated pain management models?

a. *Treatment delivery* including session formats (group, one-on-one),

duration, intensity and frequency of sessions, number of sessions; general structure and scope of sessions.

b. *Treatment components* (e.g., medication review and/or management, including transition from opioid to nonopioid medications; psychological support or mental health services; physical reconditioning, such as physical therapy and occupational therapy; use of complementary and integrative medicine treatments; patient education; use of medical procedures or devices).

c. *Care provision.*

i. Care coordination methods or decision support

ii. Provider types involved

iii. Personalization, care pathways

d. *Program characteristics.*

i. Program emphasis/goals

ii. Target population

iii. Referral sources

iv. Staffing characteristics (e.g., turn over)

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)

PICOTS	Inclusion	Exclusion
Population	<p>Medicare beneficiaries (<i>i.e.</i>, adults ≥65 years old and those under 65 years old who qualify for Medicare due to disability including ESRD) with complex acute/subacute pain^a or chronic non-active cancer pain.^b In the absence of publications in Medicare populations, studies of adults with these types of pain will be considered.</p> <p>Population subgroups of interest include those with disabilities (including ESRD), prior substance use disorder, psychological co-morbidities (including suicidal behaviors), degree of nociplasticity.^c</p>	<ul style="list-style-type: none"> • Patients undergoing end-of-life care, terminally ill (<i>e.g.</i>, hospice) patients; those under supervised palliative care. • Young, non-disabled populations.
Intervention	<p>Pain management programs that address the biopsychosocial model of pain and include:</p> <ul style="list-style-type: none"> • Multidisciplinary (interdisciplinary) teams that at a minimum have the following components available: Pharmacotherapy review and/or management, psychological care (mental health services), and physical reconditioning (<i>e.g.</i>, PT, OT); studies may also include other components in addition to these; <i>and</i> • Description of care coordination, case management or mechanisms of multidisciplinary, interdisciplinary collaboration and communication. <p>Integrated pain management programs (IPMPs) will be defined as those that include the above and are based in primary care. Comprehensive pain management programs (CPMPs) will be defined as those including the above but are not based in primary care.</p>	<ul style="list-style-type: none"> • Unimodal pain management. • Pain management confined to a single provider type, practice, or isolated method of management. • Programs focused on functional restoration and/or occupational health focused on return to work such as work hardening programs, unless they are specifically done in a Medicare eligible population or are clearly applicable to the Medicare population. • Programs in very young and non-disabled populations (<i>e.g.</i>, military populations). • Studies evaluating incremental value of adding a single treatment modality to another single treatment modality (<i>e.g.</i>, addition of CBT to PT). • Post-operative or post-trauma rehabilitation programs.
Comparator	Any.	None.
Outcome	<p>Patient oriented outcomes:</p> <ul style="list-style-type: none"> • <i>Primary:</i> Pain, function (focus on “success” if reported), opioid use. • <i>Secondary:</i> HRQOL, emotional function (<i>e.g.</i>, depression, anxiety), patient satisfaction, global improvement. <p>Harms, adverse events, unintended consequences Program-related outcomes:</p> <ul style="list-style-type: none"> • Utilization (<i>e.g.</i>, pain-related hospital/ED visits or short-term skilled nursing facility use, long term care facility or institutional care transfer, Medicaid enrollment). 	<p>Patient-oriented outcomes:</p> <ul style="list-style-type: none"> • Non-validated instruments for outcomes (<i>e.g.</i>, pain, function, HRQOL, depression, etc.) • Intermediate outcomes (<i>e.g.</i>, range of motion, physical strength, etc.).

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

PICOTS	Inclusion	Exclusion
Timing	Duration of follow up: Focus on persistence of effects evaluated short term (1 to <6 months), intermediate term (≥6 to <12 months) and long term (≥12 months) following intervention.	
Setting	Outpatient, inpatient, institutional residence.	<ul style="list-style-type: none"> • Inpatient or outpatient settings exclusively providing treatment for SUD/ODU or tertiary care, hospice, or similar settings. • Case reports. • Case series (unless no comparative studies). • Case-control studies, cross-sectional studies. • Conference proceedings, editorials, letters, white papers, citations that have not been peer-reviewed.
Study design, publication type.	Inclusion will focus on RCTs. Prospective cohort studies that control for confounding will be considered if RCTs are not available. Comparative cohorts that do not control for confounding will be considered if cohorts controlling for confounding are not available. In the absence of comparative studies, single arm (e.g., case series, pre-post studies) will be considered if they are clearly relevant to the Medicare population.	

CBT = Cognitive Behavioral Therapy; ED = emergency department; ESDR = end stage renal disease; HRQOL = Health-related quality of life; OT = occupational therapy; OUD = opioid use disorder; PICOTS = population, intervention, comparator, outcomes, timing, study design; PT = physical therapy; RCT = randomized control trial; SUD = substance use disorder.

^aComplex acute or subacute pain: Patients with acute pain (<6 weeks duration) or subacute pain (6 weeks to 12 weeks duration) who are at risk of developing chronic pain).

^bChronic, nonactive cancer pain (based on Mersky 1994): Pain that persists for at least three months and is not associated with [active] malignant disease"; pain could, however, be resultant from a previous malignancy that is no longer active.

^cThe term nociplasticity has been used to describe pain resulting from altered nociception without underlying tissue damage resulting in hypersensitivity (e.g., fibromyalgia). Many pain conditions may have a nociplastic component. Some additional terms used in the literature include centralized pain and amplified pain.

Dated: November 13, 2020.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2020-0117]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web.

DATES: The meeting will be held on November 23, 2020 from 12:00 p.m. to 5:00 p.m., EST (times subject to change).

Written comments must be received on or before November 23, 2020.

ADDRESSES: For more information on ACIP please visit the ACIP website:

<http://www.cdc.gov/vaccines/acip/index.html>.

You may submit comments, identified by Docket No. CDC-2020-0117 by any of the following methods:

- *Federal eRulemaking Portal:*

<https://www.regulations.gov>. Follow the instructions for submitting comments.

- Mail: Docket No. CDC-2020-0117, c/o Attn: November 23, 2020 ACIP Meeting, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24-8, Atlanta, GA 30329-4027.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the <https://www.regulations.gov> suitability policy will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

Written public comments submitted by 24 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road, NE, MS-H24-8, Atlanta, GA 30329-4027; Telephone: 404-639-8367; Email: ACIP@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition,

under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on COVID-19 vaccines. No recommendation vote is scheduled for COVID-19 vaccines. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>.

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: <http://www.cdc.gov/vaccines/acip/index.html>.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials are part of the public record and are subject to