Regulatory Review

HHS | Hart Health Strategies Inc.

September 12, 2016

CMS Announces "Pick Your Pace" Options for Clinicians in Proposed Quality Payment Program

Last week, Centers for Medicare and Medicaid Services (CMS) Acting Administrator Andy Slavitt announced in a blog post that it would offer physicians flexibility in how they could meet requirements and avoid financial penalties under Medicare's newly proposed Quality Payment Program (QPP), which encompasses new value-driven physician payment mechanisms established under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 – the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs).

"In recognition of the wide diversity of physician practices, we intend for the Quality Payment Program to allow physicians to pick their pace of participation for the first performance period that begins January 1, 2017," Slavitt explains. "During 2017, eligible physicians and other clinicians will have multiple options for participation. Choosing one of these options would ensure you do not receive a negative payment adjustment in 2019."

The blog post discusses four avenues for clinician participation in the proposed QPP. Under the first option, clinicians could test the quality payment program.

"With this option, as long as you submit some data to the Quality Payment Program, including data from after January 1, 2017, you will avoid a negative payment adjustment."

The blog post does not describe which categories of data must be submitted or how much data will be required to meet the "submit some data" threshold.

Under the second option, clinicians could participate for part of the calendar year and qualify for a small positive payment adjustment.

Under the third option, clinicians would participate for the full calendar year and earn a modest positive payment adjustment.

The fourth option calls for participation in advance alternative payment models, such as a Track 2 or 3 Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO).

Based on the blog post, CMS is not planning to delay the start date for its QPP beyond January 1, 2017. CMS also notes that it will be releasing the MIPS/APMs final rule on or about November 1, 2016, which is when "[t]hese options and other supporting details will be described fully".

The Quality Calendar

The National Quality Forum (NQF) announced the following deadlines for submitting measures to and comments on NQF projects, as well as upcoming in-person, web and teleconference meetings.

VOTE
Cancer Project 2015-2017 – *through September 21*

COMMENT
Cardiovascular 2016-2017 – *through September 19*
Variation in Measure Specifications Project 2015-2016 – *through October 5*
Patient Safety Project 2015-2017 – *through October 7*
Common Formats for Patient Safety Data: Event Reporting - Hospital Version 2.0 – *Open comment process*
Common Formats for Patient Safety Data: Surveillance - Hospital - Event Reporting - Retail Pharmacy Version 0.1 Beta – *Open comment process*
Common Formats for Patient Safety Data: Hospital Version 1.2 and 1.1, Nursing Home Version 0.1 Beta - General Comment – *Open comment process*

MEETINGS
Health and Well-Being 2015-2017 In-person Meeting – *September 12-13*
CSAC Conference Call – *September 13*
All MAP Orientation Web Meeting – *September 14*
Save the Date: NQF's Annual Conference, "Accelerating the National Agenda for Quality Measurement and Value," *April 4-5, 2017*, Arlington, VA

The National Committee for Quality Assurance (NCQA) has also opened registration for its 2016 Quality Talks, which will be hosted in Washington, DC October 24, 2016.

As a reminder, CMS regularly updates its Measures Management System website with opportunities for stakeholders to engage in CMS' quality improvement projects by nominating individuals to serve on Technical Expert Panels (TEPs), comment on quality measurement projects, or submit ideas for quality measures for CMS' multiple quality improvement programs. CMS seeks public comment on the following projects:

- Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance – through September 15, 2016

CMS also seeks TEP nominations for the following projects:

- CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) – through September 15, 2016

Requests for Nominations

Agency	Committee	Nomination Due Date
CDC	Advisory Committee to the Director, Centers for Disease Control and Prevention (ACD,CDC)-Health Disparities Subcommittee	September 30, 2016
CDC	Advisory Committee on Breast Cancer in Young Women	October 7, 2016
CDC	Advisory Committee on Immunization Practices (ACIP)	November 4, 2016
HRSA	National Advisory Council on Migrant Health	Continuous
HRSA	Advisory Commission on Childhood Vaccines	Continuous
HRSA	Council on Graduate Medical Education	Continuous
NIST	Flow Cytometry Quantitation Consortium	Continuous
HRSA	Advisory Committee on Training in Primary Care Medicine and Dentistry	Continuous

Upcoming Federal Regulatory Meetings

Agency	Meeting	Date	Location/Other Logistics
AHRQ	Subcommittees that are a part of AHRQ's Health Services Research Initial Review Group Committee	Dates and locations can be found here	
AHRQ	Health Services Research Initial Review Group Committee	Dates and locations can be found here	
CDC	Healthcare Common Procedure Coding System (HCPCS) public meetings	Dates and locations can be found here	
CDC	ICD-10 Coordination and Maintenance (C&M) Committee	September 13-14, 2016, 9 am – 5 pm	Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244
CDC	***Board of Scientific Counselors, Office of Infectious Diseases***	***September 27, 2016, 8 am – 12 pm; September 28, 2016, 8:30 am – 5 pm***	***CDC, Global Communications Center, 1600 Clifton Road NE., Building 19, Auditorium B3, Atlanta, Georgia 30333***
CDC	Community Preventive Services Task Force	October 27, 2016, 8:30 am – 1 pm	CDC Edward R. Roybal Campus, Tom Harkin Global Communications Center (Building 19), 1600 Clifton Road NE., Atlanta, GA 30329
CMS	Healthcare Common Procedure Coding System	Dates and locations can be found here	
FDA	Sequencing Quality Control II	September 13 and 14, 2016, 8 am – 5 pm	Wilson Hall, Bldg. 1, National Institutes of Health (NIH), 31 Center Dr., Bethesda, MD 20892
FDA	National Mammography Quality Assurance Advisory Committee	September 15, 2016, 8:30 am – 4:30 pm	Hilton Washington, DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877
FDA	Anesthetic and Analgesic Drug Products Advisory Committee, the Drug Safety and Risk Management Advisory Committee, and the Pediatric Advisory Committee	September 15, 2016, 8 am – 5 pm; September 16, 2016, 8 am – 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Oncologic Drugs Advisory Committee	September 14, 2016, 8 am – 1 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee	September 14, 2016, 8 am – 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Pediatric Advisory Committee	September 14, 2016, 8 am – 5:30 pm	DoubleTree by Hilton Hotel Bethesda-Washington DC, 8120 Wisconsin Ave., Bethesda, MD 20814, 301-652-2000
FDA	Public workshop regarding anti-infective drug development for neonates and young infants	September 15, 2016, 8:30 am – 4:30 pm	Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910
FDA	General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee	September 20 and 21, 2016, 8 am – 6 pm	Hilton Washington, DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877
FDA	Pediatric Master Protocols	September 23, 2016, 8:30 am – 4:30 pm	FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests	September 23, 2016, 9 am – 3 pm	Masur Auditorium at the NIH Campus, 9000 Rockville Pike, Bldg. 10, Bethesda, MD 20814

Agency	Meeting	Date	Location/Other Logistics
FDA	Patient-Focused Drug Development for patients who have received an organ transplant	September 27, 2016, 9 am – 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm.1503), Silver Spring, MD 20993-0002
FDA	FDA Small Business and Industry Assistance Regulatory Education for Industry (REdI) Fall Conference	September 27 and 28, 8:15 am – 4:15 pm	Sheraton Silver Spring Hotel, 8777 Georgia Ave., Cypress and Magnolia Ballrooms (4th floor), Silver Spring, MD 20910
FDA	Controlling the Progression of Myopia: Contact Lenses and Future Medical Devices	September 30, 2016, 8 am – 6 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room, (Rm. 1503), Silver Spring, MD, 20993
FDA	Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee	October 5, 2016, 8 am – 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Microbiology Devices Panel of the Medical Devices Advisory Committee	October 5, 2016, 8 am – 6 pm	Gaithersburg Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879
FDA	Pre-Clinical Evaluation of Red Blood Cells for Transfusion	October 6, 2016, 8 am – 5 pm; October 7, 2016, 9 am – 1 pm	Ruth Kirschstein Auditorium, Natcher Conference Center, Bldg. 45, National Institutes of Health Campus, 9000 Rockville Pike, Bethesda, MD 20892
FDA	Vaccines and Related Biological Products Advisory Committee	October 13, 2016, 1 pm – 4:30 pm	Teleconference and FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Bone, Reproductive and Urologic Drugs Advisory Committee	October 19, 2016, 8;15 am – 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Public workshop and an opportunity for public comment on Erythropoietic Protoporphyria	October 24, 2016, 10 am – 4 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Allergenic Products Advisory Committee	October 27, 2016, 1 pm – 4:20 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers	October 27, 2016, 8:30 am – 5 pm; October 28, 2016, 8:30 am – 4 pm	FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	***Science Advisory Board (SAB) to the National Center for Toxicological Research***	***November 1, 2016, 8 am – 5:30 pm; November 2, 2016, 8 am – 11:40 a.m.***	***Crowne Plaza Hotel, 201 S. Shackleford Rd., Little Rock, AR 72211***
FDA	Antimicrobial Drugs Advisory Committee	November 4, 2016, 8:30 am – 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Public hearing to obtain input on issues related to communications by manufacturers, packers, and distributors, including their representatives (collectively "firms"), regarding FDA-regulated drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs	November 9 am 10, 2016, 9 am – 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002
FDA	Vaccines and Related Biological Products Advisory Committee	November 16, 2016, 8:30 am – 2:30 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD, 20993-0002

Agency	Meeting	Date	Location/Other Logistics
FDA	***Blood Products Advisory Committee***	***November 17, 2016, 8 am – 5:30 pm; November 18, 2016, 8:30 am – 1 pm***	***FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD, 20993-0002***
FDA	The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program	December 7, 2016, 8:30 am – 5 pm	National Institutes of Health, 8600 Rockville Pike, Lister Hill Center Auditorium, Building 38A, Bethesda, MD 20894
HHS	National Cancer Advisory Board (NCAB) and NCI Board of Scientific Advisors (BSA)	Further details about meeting dates and times can be found here.	
HHS	Advisory Council on Blood Stem Cell Transplantation	September 14, 2016, 8 am – 12:30 pm	Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202
HHS	Physician-Focused Payment Model Technical Advisory Committee	September 16, 2016, 9 am – 12:30 pm	Senate Meeting Room at the Residence Inn, 333 E Street SW., Washington, DC 20024
HHS	Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria	September 19, 2016, 12:30 pm – 5:30 pm	U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW., Washington, DC 20201 and via webcast
HHS	National Vaccine Advisory Committee	September 20, 2016	U.S. Department of Health and Human Services, Hubert H. Humphrey Building, the Great Hall, 200 Independence Avenue SW., Washington, DC 20201 and via webcast
HHS	Advisory Panel on Outreach and Education	September 21, 2016, 8:30 am – 4 pm	U.S. Department of Health & Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 425A, Conference Room, Washington, DC 20201
HHS	Advisory Group on Prevention, Health Promotion, and Integrative and Public Health	September 26, 2016, 8:45 am – 5 pm	CDC Washington Office, Room 9000, 395 E Street SW., Washington DC 20201 and via teleconference
HHS	Presidential Advisory Council on HIV/AIDS	September 26, 2016, 1:30 pm – 5 pm; September 27, 2016, 9 am – 12 pm	200 Independence Avenue SW., Washington, DC 20201 in the Penthouse (eighth floor), Room 800
HHS	Guidance related to the Federal Select Agent Program	November 9, 2016, 12 pm – 4 pm	Webcast
HHS	National Committee on Vital and Health Statistics	Meeting dates and times can be found here.	
NIH	AIDS Research Advisory Committee	Further details about meeting places and times can be found here	
NIH	National Advisory Council on Minority Health and Health Disparities	September 13, 2016, 8 am – 2:30 pm	National Institutes of Health, 31 Center Drive, Building 31, 6th Floor, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892
NIH	National Arthritis and Musculoskeletal and Skin Diseases Advisory Council	September 13, 2016, 8:30 am – 12 pm	National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Conference Room 6, Bethesda, MD 20892
NIH	National Advisory Council for Nursing Research	September 13, 2016, 1 pm – 4:50 pm	National Institutes of Health, Porter Neuroscience Research Center, Building 35A, Convent Drive, 1st Floor, Room 620/630, Bethesda, MD 20892
NIH	Board of Regents of the National Library of Medicine	September 13, 2016, 9 am – 4:30 pm; September 14, 2016, 9 am – 12 pm	National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892

Agency	Meeting	Date	Location/Other Logistics
NIH	National Advisory Neurological Disorders and Stroke Council	September 15, 2016, 8 am – 2:30 pm	National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Room 10, Bethesda, MD 20892
NIH	National Center for Advancing Translational Sciences	September 15, 2016, 8:30 am – 2:30 pm	National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892
NIH	CRIC and CKiD: Using longitudinal CKD cohort study findings to plan population health interventions	September 19, 2016, 9 am – 12 pm	Natcher Conference Center on the NIH Campus at 9000 Rockville Pike, Bethesda, MD 20894
NIH	National Advisory Mental Health Council	September 20, 2016, 9 am – 1 pm	National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852
NIH	National Heart, Lung, and Blood Advisory Council	September 20, 2016, 1 pm – 5 pm	National Institutes of Health, Building 35A, Porter Building, Room 640, 35A Convent Drive, Bethesda, MD 20892
NIH	Sickle Cell Disease Advisory Committee	September 23, 2016, 8:30 am – 3 pm	National Institutes of Health, 6701 Rockledge Drive, 9th Floor, Room 9112/9116, Bethesda, MD 20892
NIH	National Cancer Institute Council of Research Advocates	September 26, 2016, 9 am – 4:30 pm	National Institutes of Health, 35 Convent Drive, Building 35, Conference Rooms 620/630, Bethesda, MD 20892
NIH	National Advisory Council on Aging	September 28, 2016, 8 am – 12:45 pm	National Institutes of Health, Building 31, C Wing 6th Floor Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892
NIH	***National Advisory Council on the National Health Service Corps***	***September 28, 2016, 12 pm – 3:30 pm***	***U.S. Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Conference Call Format***
NIH	Board of Scientific Counselors, National Institute on Aging	October 11-13, 2016	National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room, 251 Bayview Boulevard, Baltimore, MD 21224
NIH	Literature Selection Technical Review Committee	October 27, 2016, 8:30 am – 10:45 am	National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20894
NIH	National Cancer Institute Clinical Trials and Translational Research Advisory Committee	November 2, 2016, 8 am – 4 pm	National Institutes of Health, Building 31, C-Wing, 6th Floor, Room 9 and 10, 31 Center Drive, Bethesda, MD 20892
NIH	Board of Scientific Counselors, National Center for Biotechnology	November 15, 2016, 8:30 am – 12 pm	National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892
NIST	Manufacturing Extension Partnership (MEP) Advisory Board	September 15, 2016, 8 am – 3:30 pm	Detroit Marriott at the Renaissance Center, 400 Renaissance Dr. W., Detroit, Michigan 48243
ONC	Health IT Policy Committee	Further details about meeting places and times can be found here.	
ONC	Health IT Standards Committee	Further details about meeting places and times can be found here.	
VA	Health Services Research and Development Service Scientific Merit Review Board	Dates can be found here	Sheraton Suites Old Town, 801 North St. Asaph Street, Alexandria, VA 22314
VA	Health Services Research and Development Service Scientific Merit Review Board	Dates can be found here	Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, VA, 22314

Agency	Meeting	Date	Location/Other Logistics
VA	Subcommittees of the Rehabilitation Research and Development Service Scientific Merit Review Board	Multiple sub-committees and meeting dates: April 9, 2016	VHA National Conference Center, 2011 Crystal Drive, Arlington, VA 22202.
VA	Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board	Further details about meeting places and times can be found here.	
VA	Health Services Research and Development Service Scientific Merit Review Board	Further details about meeting places and times can be found here.	

Opportunities for Public Comment & Federal Agency Notices

Federal Rules, Regulations and Notices	Effective Date	Comments Due
Issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Zika virus in response to the Zika virus outbreak in the Americas	***July 19, 2016***	
PREVACID IV (lansoprazole) intravenous injection, 30 milligrams (mg)/vial, was not withdrawn from sale for reasons of safety or effectiveness	***September 8, 2016***	
The invention Reagent for Mapping Genome-Wide Enhancer-Promoter Interactions is owned by an agency of the U.S. Government and are available for licensing in the U.S.	***September 9, 2016***	
Final rule revising medical device and certain biological product labeling regulations to explicitly allow for the optional inclusion of graphical representations of information, or symbols, in labeling (including labels) without adjacent explanatory text (referred to in this document as "stand-alone symbols") if certain requirements are met	September 13, 2016	
Medicare Participation Agreement for Physicians and Suppliers		September 13, 2016
Study of the Global Cancer Project Map		September 13, 2016
Proposed rule addresses the hospital-specific limitation on Medicaid disproportionate share hospital (DSH) payments		September 14, 2016
Applications for FDA Approval To Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed		September 14, 2016
Amendment of the general biological products standards relating to dating periods and also removing certain standards relating to standard preparations and limits of potency	September 16, 2016	
$100,000 for Start a SUD Startup" Challenge		September 16, 2016
Emergency Epidemic Investigation Data Collections		September 16, 2016
Generic Clearance for CDC/ATSDR Formative Research and Tool Development		September 16, 2016
Importation of Etiologic Agents		September 16, 2016
Administrator of the WTC Health Program has identified potential improvements to certain existing provisions, including, but not limited to, appeals of enrollment, certification, and treatment decisions, as well as the procedures for the addition of health conditions for WTC Health Program coverage		September 16, 2016
Indirect Medical Education and Supporting Regulations		September 19, 2016
Solicitation of comments on the collection of information related to certain regulations that provide protection for human subjects of clinical investigations conducted in support of applications or submissions to FDA for FDA-regulated products		September 19, 2016
Export of Medical Devices; Foreign Letters of Approval		September 19, 2016
Mammography Quality Standards Act Requirements		September 19, 2016

Federal Rules, Regulations and Notices	Effective Date	Comments Due
Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations; Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations; Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death; Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-party Submission Authorization Form; Physician Certification/Recertification in Skilled Nursing Facilities (SNFs) Manual Instructions; Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey, Focus Groups, and Informational Interviews; and Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments		September 20, 2016
Supporting Youth Living with HIV		September 21, 2016
Data Collection Tool for State Offices of Rural Health Grant Program		September 21, 2016
Solicitation of comments on a range of issues pertaining to the Black Lung Clinics Program		September 21, 2016
Traumatic Brain Injury (TBI) Surveillance System		September 22, 2016
Solicitation of public comment regarding concerns about health care providers and provider-affiliated organizations steering people eligible for or receiving Medicare and/or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates		September 22, 2016
Request for Employment Information		September 23, 2016
Report of a Hospital Death Associated with Restraint or Seclusion; and Procedures for Making National Coverage Decisions		September 23, 2016
Standardized National Hypothesis Generating Questionnaire		September 24, 2016
Prevalence Survey of Healthcare-Associated Infections (HAIs) and Antimicrobial Use in U.S. Acute Care Hospitals		September 24, 2016
Quality Metrics Technical Conformance Guide, Version 1.0		September 26, 2016
Airline and Vessel and Traveler Information Collection		September 26, 2016
National Health Interview Survey		September 26, 2016
National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers (NNPTC): Evaluation		September 26, 2016
Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System		September 26, 2016
Solicitation of comments on requests for feedback submitted under the Pre-Submission program for medical devices		September 26, 2016
Medicare Program/Home Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation and Documentation Requirements Concerning Emergency and Nonemergency Ambulance Transports Described in the Beneficiary Signature Regulations in 42 CFR 424.36(b)		September 27, 2016
Community-Based Organization Outcome Monitoring Projects for CBO HIV Prevention Services Clients		September 29, 2016
CDC Workplace Health Promotion Resource Center		September 29, 2016
Generic Clearance for Lyme and other Tickborne Diseases Knowledge, Attitudes, and Practices Surveys		September 29, 2016
Stem Cell Therapeutic Outcomes Database		September 29, 2016
Regulated Product Submission Table of Contents Pilot Program		September 30, 2016
2017-2021 NIDCD Strategic Plan		September 30, 2016

Federal Rules, Regulations and Notices	Effective Date	Comments Due
Federal Medical Assistance Percentages (FMAP), Enhanced Federal Medical Assistance Percentages (eFMAP), and disaster-recovery FMAP adjustments for Fiscal Year 2017 have been calculated pursuant to the Social Security Act		October 1, 2016
Listing of entities, and associated Health Professional Shortage Area (HPSA) scores, that will receive priority for the assignment of National Health Service Corps (NHSC) scholarship recipients	October 1, 2016	
Decrease in user fees charged to individuals and entities authorized to request information from the National Practitioner Data Bank	October 1, 2016	
Rates for abbreviated new drug applications (ANDAs), prior approval supplements to an approved ANDA (PASs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, and finished dosage form (FDF) facilities user fees related to the Generic Drug User Fee Program for fiscal year (FY) 2017	October 1, 2016	
Rates for biosimilar user fees for fiscal year (FY) 2017	October 1, 2016	
Rates for prescription drug user fees for fiscal year (FY) 2017	October 1, 2016	
Fee rates and payment procedures for medical device user fees for fiscal year (FY) 2017	October 1, 2016	
Prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities	October 1, 2016	
Final rule updating the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2017	October 1, 2016	
Final rule updating the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2017	October 1, 2016	
Final rule updating the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2017	October 1, 2016	
Revision of the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2017	October 1, 2016	
Countermeasures Injury Compensation Program		October 2, 2016
Proposed rule proposing to implement three new Medicare Parts A and B episode payment models under section 1115A of the Social Security Act		October 3, 2016
The Patient-Centered Medical Home (PCMH) Items Demonstration Study		October 3, 2016
Certification of Identity for Freedom of Information Act and Privacy Act Requests		October 3, 2016
Examination and Treatment for Emergency Medical Conditions and Women in Labor; and HIPAA Administrative Simplification Complaint Form		October 3, 2016
Collection of Encounter Data From: Medicare Advantage Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and PACE Organizations and The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460		October 4, 2016
Invitation for public comment as the Agency considers a user-fee program for nonprescription (over-the-counter or OTC) monograph drugs		October 6, 2016
Strike the Right Balance Between Premarket and Postmarket Data Collection		October 7, 2016
Requests for Clinical Laboratory Improvement Amendments of 1988 Categorization		***October 7, 2016***
Agency for Healthcare Research and Quality's (AHRQ) Guide To Improving Patient Safety in Primary Care Settings by Engaging Patients and Families—Evaluation		October 11, 2016
Proposed study to examine the facilitators and barriers to receiving clinical preventive services among newly insured medically underserved women who had previously been served by the National Breast and Cervical Cancer Early Detection Program		October 11, 2016
Behavioral Risk Factor Surveillance System (BRFSS) Asthma Call-back Survey		October 11, 2016
Information Collection for Tuberculosis Data from Referring Entities to CureTB		October 11, 2016
Survey of Surveillance Records of Aedes aegypti and Aedes albopictus from 1960 to Present		October 11, 2016

Federal Rules, Regulations and Notices	Effective Date	Comments Due
Office for the Advancement of Telehealth Outcome Measures		October 11, 2016
Proposed rule sets forth the requirements and procedures for the 340B Program's administrative dispute resolution process		October 11, 2016
Postmarket Surveillance		***October 11, 2016***
Medicare Self-Referral Disclosure Protocol		***October 11, 2016***
Small Rural Hospital Transitions Project		***October 11, 2016***
National Toxicology Program (NTP) requests information on four nominations; Four substances are being considered for possible review for future editions of the Report on Carcinogens		***October 11, 2016***
Availability of grant funds for the support of FDA's Office of Orphan Products Development (OOPD) Natural History Grants Program		October 14, 2016
Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is amending its domestic (interstate) and foreign quarantine regulations to best protect the public health of the United States		October 14, 2016
CDC Undergraduate Scholars Program (CUPS), James A. Ferguson Infectious Diseases Graduate Fellowship (Ferguson) and Student Coordinating Center (SCC) Program Evaluation		October 17, 2016
Proposed rule would revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs		October 17, 2016
Initial Request for State Implemented Moratorium Form and Children's Health Insurance Program (CHIP) Report on Payables and Receivables		October 17, 2016
Materials to support the NIH Serving As an Institutional Review Board (IRB) of Record or a Single IRB for Outside Institutions		October 21, 2016
A National Survey of Nurse Coaches		October 21, 2016
Report of Verified Case of Tuberculosis		October 24, 2016
Alzheimer's Disease Supportive Services Program and expansion of collection to include ACL grantees of the Alzheimer's Disease Initiative—Specialized Supportive Services		October 24, 2016
Medical Countermeasures.gov		October 24, 2016
The National Health Service Corps Loan Repayment Program		October 28, 2016
Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)		November 1, 2016
Final vaccine information materials for hepatitis A and hepatitis B vaccines	***November 1, 2016***	
Final vaccine information materials for polio vaccine	***November 1, 2016***	
Solicitation of comments on the information collection requirements for FDA regulations related to human cells, tissues, and cellular and tissue-based products (HCT/Ps) involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice		***November 7, 2016***
National Tissue Recovery through Utilization Survey		***November 7, 2016***
Medicare Quality of Care Complaint Form		***November 7, 2016***
Solicitation of comments on recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation		***November 7, 2016***
Proposal to amend the regulations for good laboratory practice (GLP) for nonclinical laboratory studies to require a complete quality system approach, referred to as a GLP Quality System, when safety and toxicity studies support or are intended to support applications or submissions for products regulated by FDA		November 22, 2016
Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry		November 25, 2016

Federal Rules, Regulations and Notices	Effective Date	Comments Due
Regulations governing drug establishment registration and drug listing	November 29, 2016	
Final vaccine information materials for serogroup B meningococcal vaccine	***December 1, 2016***	
Proposed rule to amend the 1994 tentative final monograph or proposed rule (the 1994 TFM) for over-the-counter (OTC) antiseptic drug products		December 27, 2016
Methodology and data sources necessary to determine Federal payment amounts made in program years 2017 and 2018 to states that elect to establish a Basic Health Program	Jan. 1, 2017	
"Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Test" Challenge		***Jan. 9, 2017***
Policy on the use of a single Institutional Review Board (IRB) for multi-site research to establish the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States	May 25, 2017	

FDA Guidance Documents

Guidance Title	Stage	Comments Due
Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions	Draft	September 14, 2016
Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies	Draft	September 19, 2016
Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)	Draft	September 26, 2016
Extension of the comment period for the draft guidance documents entitled "Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry"; "Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff"; "Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry"; and "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff."	Draft	September 27, 2016
Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees; Guidance for the Public, FDA Advisory Committee Members, and FDA Staff	Draft	September 27, 2016
Vulvovaginal Candidiasis: Developing Drugs for Treatment	Draft	September 29, 2016
Recurrent Herpes Labialis: Developing Drugs for Treatment and Prevention	Draft	September 29, 2016
Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs	Draft	October 3, 2016
Insanitary Conditions at Compounding Facilities	Draft	October 3, 2016
Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics	Draft	October 6, 2016
Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases	Draft	October 6, 2016
Ulcerative Colitis: Clinical Trial Endpoints	Draft	October 7, 2016
Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act	Draft	October 11, 2016
Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act	Draft	October 11, 2016
Bacterial Vaginosis: Developing Drugs for Treatment	Draft	October 12, 2016

Guidance Title	Stage	Comments Due
Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product	Draft	October 13, 2016
Regulatory Classification of Pharmaceutical Co-Crystals	Draft	October 17, 2016
Draft Guidance on Fidaxomicin	Draft	October 24, 2016
Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices	Draft	October 25, 2016
Bioequivalence Recommendations for Risperidone	Draft	October 31, 2016
Medical X-Ray Imaging Devices Conformance With IEC Standards	Draft	November 1, 2016
Deciding When to Submit a 510(k) for a Change to an Existing Device	Draft	November 7, 2016
Deciding When to Submit a 510(k) for a Software Change to an Existing Device	Draft	November 7, 2016
E17 General Principles for Planning and Design of Multi-Regional Clinical Trials	***Draft***	***November 8, 2016***
ICH S3A Guidance: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies—Questions and Answers	***Draft***	***December 7, 2016***
Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices	Final	Anytime
Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry	Final	Anytime

Pending OMB Review

Agency	Title	Stage	Received Date
CDC	Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review, Addition of Certain Influenza Strains to the List of Select Agents, and Enhanced Biosafety Requirements	Final Rule	August 18, 2016
CMS	Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics	Proposed Rule	April 27, 2016
CMS	Medicaid Supplemental Payment and Accountability	Proposed Rule	July 19, 2016
CMS	Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid, and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP	Proposed Rule	August 5, 2016
CMS	Fire Safety Requirements for Certain Dialysis Facilities	Proposed Rule	September 2, 2016
CMS	Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid, and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP	Final Rule	August 5, 2016
CMS	Conditions of Participation for Home Health Agencies	Final Rule	May 6, 2016
CMS	Reform of Requirements for Long-Term Care Facilities	Final Rule	August 16, 2016
CMS	Pre-Existing Condition Insurance Plan Program Updates	Interim Final Rule	February 3, 2016
HRSA	340B Program Omnibus Guidelines	Notice	September 1, 2016
HRSA	***Definition of Human Organ Under Section 301 of the National Organ Transplant Act of 1984***	***Final Rule***	***September 9, 2016***
NIH	Clinical Trials Registration and Results Submission	Final Rule	August 1, 2016
OIG	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing	Final Rule	August 16, 2016
OIG	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of the Inspector General's Civil Monetary Penalty Rules	Final Rule	August 16, 2016
ONC	ONC Health IT Certification Program: Enhanced Oversight and Accountability	Final Rule	August 18, 2016