National Conference of State Legislatures Office of State-Federal Relations
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SELECTED HEALTH REGULATIONS AND OTHER GUIDANCE'S
Updated June 12, 2017

Key to Terms/Acronyms:

Patient Protection and Affordable Care Act (ACA)
Centers for Consumer Information and Insurance Oversight (CCIIO)
Centers for Medicaid and Medicare Services (CMS)
Children's Health Insurance Program (CHIP)
Children's Health Insurance Program Reauthorization Act (CHIPRA)
Department of Labor (DOL)
Health Resources and Services Administration (HRSA)
Employment Services Benefit Administration (ESBA)
Internal Revenue Service (IRS)
Notice of Proposed Rulemaking (NPRM)
Small Business Options Program (SHOP) Exchange
U.S. Department of Health and Human Services (HHS)

REGULATION/AGENCY/ PUBLIC LAW	ACTION	DESCRIPTION	DATE FILED	PUBLISHED IN FEDERAL REGISTER	COMMENT PERIOD ENDS	EFFECTIVE DATE
Public Comment Request; Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation **HRSA/HHS**	Notice.	The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, an agency of HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living donations and is required to submit to Congress an annual report on the long-term health effects of living donation. The SRTR contractor will establish a pilot living donor registry in which 14 transplant programs will register all potential living donors who provide informed consent to participate in the pilot registry.	10/04/2017	10/05/2017	11/06/2017	

REGULATION/AGENCY/ PUBLIC LAW	ACTION	DESCRIPTION	DATE FILED	PUBLISHED IN FEDERAL REGISTER	COMMENT PERIOD ENDS	EFFECTIVE DATE
Medicare and Medicaid Programs; Revisions to Certain Patient's Rights Conditions for Participation and Conditions for Coverage; Withdrawal **CMS/HHS**	Withdraw of proposed rule.	Withdraws a proposed rule that was published on December 12, 2014. This proposed rule would revise the applicable conditions of participation for certain providers, conditions for coverage for certain suppliers, and requirements for long-term care facilities, to ensure that the requirements are consistent with the Supreme Court decision in United States v. Windsor (570 U.S.12, 133 S. Ct. 2675 (2013)), and HHS policy. Previous rule proposed to revise certain definitions and patient's rights provisions that currently defer to state law, in order to ensure that same-sex spouses are recognized and afforded equal rights in certain Medicare and Medicaid-participating facilities.	10/03/2017	10/04/2017		10/04/2017
Opioid Policy Steering Committee; Establishment of a Public Docket; **FDA**	Request for Comment.	The FDA is soliciting suggestions, recommendations, and comments from interested parties, including patients and patient representatives, health care professionals, academic institutions, regulated industry, and other interested organizations, on questions relevant to FDA's newly established Opioid Policy Steering Committee (OPSC). They are especially interested in hearing from interested parties in three key areas: What more can FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions; what steps can FDA take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice; and should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?	09/28/2017	09/29/2017	12/28/2017	
Head Start Program; background checks procedures. **OHS/ACF/HHS**	Final Rule; delay of compliance date.	The Office of Head Start will delay the compliance date for background check procedures and the date for programs to participate in their state or local Quality Rating and Improvement Systems (QRIS). Both requirements are described in the Head Start Program Performance Standards (HSPPS) final rule that was published in the Federal Register on September 6, 2016. This will give programs and states more time to fully implement these changes.	09/27/2017	09/28/2017		09/30/2018

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Request for Comments on the Draft Department HHS Strategic Plan for FY 2018-2022 **HHS**	Request for comments.	The Department of Health and Human Services (HHS) is seeking public comment on its draft Strategic Plan for Fiscal Years 2018-2022. Comment should touch on HHS' five strategic goals which are (1) Reform, Strengthen, and Modernize the Nation's Health Care System, (2) Protect the Health of Americans Where They Live, Learn, Work, and Play, (3) Strengthen the Economic and Social Well-Being of Americans across the Lifespan, (4) Foster Sound, Sustained Advances in Sciences, and (5) Promote Effective and Efficient Management and Stewardship.	09/26/2017	09/27/2017	10/26/2017	
COMPETES Reauthorization Act Challenge Competition **HRSA/HHS**	Notice.	The Health Resources and Services Administration's (HRSA's) Maternal and Child Health Bureau (MCHB) announces a prize competition to support the development and testing of low-cost, scalable technology-based innovations to meet the needs of families and health care providers of children with special health care needs (CSHCN), particularly children with medical complexity (CMC), to improve the quality of care, patient empowerment, and family experiences while saving costs to the health care system.	09/25/2017	09/26/2017	04/28/2017 (Submission Period Ends)	01/22/2018
Medical Device User Fee Rates for Fiscal Year 2018 **FDA/HHS**	Notice	The FDA annoucned the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2018, which apply from October 1, 2017, through September 30, 2018.	08/28/2017	08/29/2017		
Medicare Program; FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements **CMS/HHS**	Final Rule.	Will update the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2018. Additionally, includes new quality measures and provides an update on the hospice quality reporting program.	08/01/2017	08/04/2017	07/03/2017	10/01/2017

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Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations **CMS/HHS**	Final Rule	Announced an extension of statewide temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance providers and suppliers and Medicare home health agencies, subunits, and branch locations in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey, as applicable, to prevent and combat fraud, waste, and abuse. Extension also applies to the enrollment of new non-emergency ground ambulance suppliers and home health agencies, subunits, and branch locations in Medicaid and the Children's Health Insurance Program in those states.	07/27/2017	07/28/2017		07/29/2017
Medicaid Program; State Disproportionate Share Hospital Allotment Reductions **CMS/HHS**	Proposed Rule.	The ACA had set to amend aggregate reductions to state Medicaid disproportionate share hospital (DSH) allotments annually from 2014 through 2020. Subsequent legislation delayed the start of these reductions until 2018. These reductions will run through 2025. This proposed rule delineates the DSH Health Reform Methodology (DHRM) to implement annual Medicaid allotment reductions identified in the statute. This rule proposes a DHRM that accounts for relevant data that was unavailable to CMS during prior rulemaking for DSH allotment reductions originally set to take place for 2014 and 2015.	07/27/2017	07/28/2017		
Medicaid/CHIP Program; Medicaid Program and Children's Health Insurance Program (CHIP); Changes to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs in Response to the Affordable Care Act **CMS/HHS**	Final Rule	Updated the Medicaid Eligibility Quality Control (MEQC) and Payment Error Rate Measurement (PERM) programs based on the changes to Medicaid and the Children's Health Insurance Program (CHIP) eligibility under the Patient Protection and Affordable Care Act. This rule also implements various other improvements to the PERM program.	06/29/2017	07/05/2017	07/28/2017	08/04/2017

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Patient Protection and Affordable Care Act (ACA: Reducing Regulatory Burdens and Improving Health Care Choices To Empower Patients **CMS**	Request for information.	(HHS) is actively working to reduce regulatory burdens and improve health insurance options under Title I of the Patient Protection and Affordable Care Act. HHS seeks comment from interested parties to inform its ongoing efforts to create a more patient-centered health care system that adheres to the key principles of affordability, accessibility, quality, innovation, and empowerment.	06/08/2017	06/12/2017	07/12/2017	
Medicare and Medicaid Programs: Long Term Care Facilities: Arbitration Agreements **CMS**	NPRM	This proposed rule would revise the requirements that Long-Term Care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. Specifically, it would remove provisions prohibiting binding pre-dispute arbitration and strengthen requirements regarding the transparency of arbitration agreements in LTC facilities. This proposal would support the resident's right to make informed choices about important aspects of his or her health care. In addition, this proposal is consistent with their approach to eliminating unnecessary burden on providers. [1]	06/05/2017	06/08/2017	08/05/2017	
340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation **HHS**	Final rule; further delay of effective date.	(HRSA) administers section 340B of the Public Health Service Act (PHSA), referred to as the "340B Drug Pricing Program" or the "340B Program." HRSA published a final rule on January 5, 2017, that set forth the calculation of the ceiling price and application of civil monetary penalties. The final rule applied to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. In accordance with a January 20, 2017, memorandum from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," HRSA issued an interim final rule that delayed the effective date of the final rule published in the Federal Register (82 FR 1210, (January 5, 2017)) to May 22, 2017. HHS invited commenters on whether a longer delay of the effective date to October 1, 2017, would be more appropriate. HHS is delaying the effective date of the final rule, to October 1, 2017.	05/18/2017	05/19/2017	05/19/2017	10/1/2017

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Medicare Program: Advancing Care Coordination Through Episode Payment Models; Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model; Delay of Effective Date **CMS**	Final rule; delay of effective date.	This rule finalizes on May 20, 2017 the "Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR)" originally published in the January 3, 2017 Federal Register. This rule also finalizes a delay of the applicability date of the regulations from July 1, 2017 to January 1, 2018 and delays the effective date of the specific CJR regulations listed in the DATES section from July 1, 2017 to January 1, 2018.[2]	01/03/2017	05/19/2017		05/19/2017 and 01/01/2018
Medicare Program: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities: Revisions to Case-Mix Methodology **CMS**	NPRM	CMS is issuing an notice of proposed rulemaking (ANPRM) to solicit public comments on potential options to consider for revising certain aspects of the existing skilled nursing facility (SNF) prospective payment system (PPS) payment methodology to improve its accuracy, based on the results of our SNF Payment Models Research (SNF PMR) project. CMS is seeking comments on the possibility of replacing the SNF PPS' existing case-mix classification model, the Resource Utilization Groups, Version 4 (RUG-IV), with a new model, the Resident Classification System, Version I (RCS-I). They will also review how such a change could be implemented, as well as several other policy changes considered to complement implementation of a new model.	12/20/2016	05/04/2017	06/26/2017	
Medicare Program: FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements **CMS**	NPRM	This proposed rule would update the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2018. Additionally, this rule proposes changes to the hospice quality reporting program, including proposing new quality measures, soliciting feedback on an enhanced data collection instrument, and describing plans to publicly display quality measures and other hospice data.	04/27/2017	05/03/2017	06/27/2017	

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Medicare Program: Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2018 **CMS**	NPRM	This proposed rule would update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2018 as required by the statute. The rule includes the classification and weighting factors for the IRF prospective payment system's (IRF PPS) case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2018. CMS is also proposing to remove the 25 percent payment penalty for inpatient rehabilitation facility patient assessment instrument (IRF-PAI) late transmissions, remove the voluntary swallowing status item (Item 27) from the IRF-PAI, revise the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes that are used to determine presumptive compliance under the "60 percent rule," and solicit comments regarding the criteria used to classify facilities for payment under the IRF PPS.	04/27/2017	05/03/2017	06/26/2017	
Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long Term Care Hospital Prospective Payment System and Proposed Policy Changes **CMS**	NPRM.	CMS is proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals. Some of these proposed changes would implement certain statutory provisions contained in the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Medicare Access and CHIP Reauthorization Act of 2015, the 21st Century Cures Act, and other legislation. Their proposals are relating to the provider-based status of Indian Health Service (IHS) and Tribal facilities and organizations and to the low-volume hospital payment adjustment for hospitals operated by the IHS or a Tribe. In addition, they are providing the proposed estimated market basket update that would apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost subject to these limits for FY 2018. They are proposing to	04/28/2017	05/28/2017	06/13/2017	

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		update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2018. Additionally they are proposing to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities) and to establish new requirements or revise existing requirements for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs.				
Patient Protection and Affordable Care Act; Market Stabilization **CMS**	Final Rule	This finalizes changes that will help stabilize the individual and small group markets and affirm the traditional role of State regulators. This final rule amends standards relating to special enrollment periods, guaranteed availability, and the timing of the annual open enrollment period in the individual market for the 2018 plan year; standards related to network adequacy and essential community providers for qualified health plans; and the rules around actuarial value requirements.	04/13/2017	04/18/2017		06/19/2017
Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies; Delay of Effective Date **CMS**	NPRM.	This proposed rule would delay the effective date for the final rule entitled "Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies" published in the Federal Register on January 13, 2017. The current effective date for the final rule is July 13, 2017, and this rule proposes to delay the effective date for an additional 6 months until January 13, 2018. This proposed rule would also make two conforming changes to dates that are included in the regulations text.	03/31/2017	04/03/2017	06/02/2017	07/13/201[3]7

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Medicaid Program: Disproportionate Share Hospital Payments-Treatment of Third Party Payers in Calculating Uncompensated Care Costs **CMS**	Final Rule	This addresses the hospital-specific limitation on Medicaid disproportionate share hospital (DSH) payments under section the Social Security Act (Act), by clarifying that the hospital-specific DSH limit is based only on uncompensated care costs. Specifically, this rule makes explicit in the text of the regulation, an existing interpretation that uncompensated care costs include only those costs for Medicaid eligible individuals that remain after accounting for payments made to hospitals by or on behalf of Medicaid eligible individuals, including Medicare and other third party payments that compensate the hospitals for care furnished to such individuals. This hospital-specific limit calculation will reflect only the costs for Medicaid eligible individuals for which the hospital has not received payment from any source.	03/30/2017	04/03/2017		06/02/2017
Confidentiality of Substance Use Disorder Patient Records **HHS**	Final rule; delay of effective date	The Substance Abuse and Mental Health Services Administration (SAMHSA) published a final rule on Confidentiality of Substance Use Disorder Patient Records. That rule is scheduled to take effect on February 17, 2017. In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," published in the Federal Register on January 24, 2017 (82 FR 8346), this action delays for 60 days from the date of the memorandum the effective date of the rule entitled "Confidentiality of Substance Use Disorder Patient Records" published in the Federal Register on January 18, 2017 (82 FR 6052).	02/15/2017	02/16/2017		03/21/2017

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Medicare Program: Changes to Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures **CMS**	Final rule.	This final rule revises the procedures that (HHS) follows at the Administrative Law Judge (ALJ) level for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries, enrollees in Medicare Advantage (MA) and other Medicare competitive health plans, and enrollees in Medicare prescription drug plans, as well as appeals of Medicare beneficiary enrollment and entitlement determinations, and certain Medicare premium appeals. In addition, this final rule revises procedures that HHS follows at CMS and the Medicare Appeals Council (Council) levels of appeal for certain matters affecting the ALJ level.	01/13/2017	01/17/2017		03/20/2017

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[1] On 10/04/2016 CMS final rule entitled "Reform of Requirements for Long-Term Care Facilities" (81 FR 68688) (2016 final rule). The 2016 final rule amended 42 CFR 483.70(n) to prohibit long-term care (LTC) facilities from entering pre-dispute arbitration agreements with any resident or his or her representative or requiring that a resident sign an arbitration agreement as a condition of admission to the LTC facility.

[2] Final rule is effective May 20, 2017, except for the provisions of the final rule contained in the following amendatory instructions, which are effective January 1, 2018: Number 3 amending 42 CFR 510.2; number 4 adding 42 CFR 510.110; number 6 amending 42 CFR 510.120; number 14 amending 42 CFR 510.405; number 15 amending 42 CFR 510.410; number 16 revising 42 CFR 510.500; number 17 revising 42 CFR 510.505; number 18 adding 42 CFR 510.506; and number 19 amending 42 CFR 510.515.

[3] The current effective date for the final rule is July 13, 2017, and this rule proposes to delay the effective date for an additional 6 months until January 13, 2018. This proposed rule would also make two conforming changes to dates that are included in the regulations text.