

M E M O R A N D U M

TO: Regulatory Department

FROM: Dianne De La Mare
Vice President of Regulatory Affairs

SUBJECT: **HHS Semiannual Regulatory Agenda**

DATE: December 15, 2008

In late November 2008, the U.S. Department of Health (HHS) released its semiannual regulatory agenda. Outlined below are some of the significant upcoming rulemaking actions under development or review. For a complete copy of the document go to <http://edocket.access.gpo.gov/ua081124/ua081104.txt>.

DHHS		Centers for Medicare & Medicaid Services (CMS)		
332.	Requirements for Long-Term Care Facilities: Hospice Services			
Legal Authority:		42 USC 1302; 42 USC 139hh		
CFR Citation :				
Abstract:		This proposed rule would establish requirements that long-term care (LTC) facilities must have an agreement with hospice agencies when hospice care is provided in a long-term care facility to participate in the Medicare and Medicaid programs. We are proposing these new requirements to ensure that quality hospice care is provided to eligible residents		
Legal Deadline:				
Timetable:		NPRM	12/00/08	
Agency Contact : Trish Brooks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-4561. Email : trish.brooks@cms.hhs.gov				
334.	Revisions to Payment Policies Under the Physician Fee Schedule for FY 2010			
Regulatory Plan:		This entry is Seq No 43 in Part II of the issue of the Federal Register		
336.	Updates to electronic transactions			
Legal Authority:		Sec 1171 to 1179 of the Social Security Act; Deficit Reduction Act of 2005		
CFR Citation				
Abstract:		This rule adopts new versions of the X12 suite of HIPAA Transactions and allows the industry to use the most up-to-date versions of the HIPAA Transactions for claims and remittance advice. The rule will also adopt an updated pharmacy transactions standard for retail pharmacy claims.		
Legal Deadline:				
Timetable:		NPRM	08/22/2008	
		NPRM Comment Period End	10/21/2008	
		Final Action	11/00/2008	
Agency Contact : Gladys C. Wheeler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of E-Health Standards and Services, Mailstop S2-24-18, 7500 Security Boulevard, Baltimore, MD 21244, 410-786-0273. Email : gladys.wheeler@cms.hhs.gov				

337.	Revisions to HIPAA Code Sets		
Legal Authority:		PL 104-191	
CFR Citation			
Abstract:		This rule revise some of the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000 and February 20, 2003	
Legal Deadline:			
Timetable:		NPRM	08/22/2008
		NPRM Comment Period End	10/21/2008
		Final Action	11/00/2008
Agency Contact : Denise Buenning, Health Insurance Specialist, Office of E-Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid, Mailstop S2-26-17, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-6711. Email : denise.buenning@cms.hhs.gov			
338.	Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F)(Section 610 Review)		
Legal Authority:		Deficit Reduction Act of 2005. PL 109-171, sec. 6086	
CFR Citation			
Abstract:		This rule amends the Medicaid regulations to define and describe the home and community-based State plan services implementing the new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005	
Legal Deadline:			
Timetable:		NPRM	04/04/2008
		NPRM Comment Period End	06/03/2008
		Final Action	11/00/2008
Agency Contact : Suzanne Bosstick, Department of Health and Human Services, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. Phone :410-786-1301. Email : suzanne.bosstick@cms.hhs.gov .			
339.	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2009		
Legal Authority:		BBA; PPARA: BIPA; MMA; 42 USC 1302 et al	
CFR Citation			
Abstract:		This rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from continuing experience with this system and to implement certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. In addition, the rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also changes to the Ambulatory Surgical Center Payment System list of services and rates. These changes would be applicable to services furnished on or after January 1 annually.	
Legal Deadline:			
Timetable:		NPRM	7/18/2008
		NPRM Comment Period End	09/02/2008
		Final Action	11/00/2008
Agency Contact : Alberta Dwivedi, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Mailstop C5-01-26, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-0763. Email : alberta.dwivedi@cms.hhs.gov .			

340.	Home Health Prospective Payment System Refinements and Rate Update for CY 2009		
Legal Authority:		Social Security Act, sec. 1102 and 1871; (42 USC 1302 and 1395(hh)); Social Security Act, sec. 1895 (42 USC 1395 fff)	
CFR Citation			
Abstract:		Section 1895 of The Act that the Home Health PPS be adjusted in a prospective manner specified by the Secretary by the home health increase percentage applicable to the year involved.	
Legal Deadline:			
Timetable:		Notice:	11/01/08
Agency Contact : Randy Thronset, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5-07-28, 7500 Security Boulevard, Baltimore MD 21244. Phone : 410-786-0131. Fax : 410-786-0765. Email : randy.thronset@cms.hhs.gov			
341.	Home Health Agency (HHA) Conditions of Participation		
Legal Authority:		42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb	
CFR Citation			
Abstract:		This proposed rule would revise the existing Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.	
Legal Deadline:			
Timetable:		NPRM NPRM Comment Period End Second NPRM	3/10/1997 06/09/2007 TBD
Agency Contact : Commander Mercedes Benitez-McCrary, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Clinical Standards Group, Mailstop S3-05-14, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-5716. Email : mercedes.benitezmcrary@cms.hhs.gov			
342.	Electronic Claims Attachments Standards		
Legal Authority:		42 USC 1320d-2(a)(2)(b)	
CFR Citation			
Abstract:		This rule sets forth electronic standards for health care claims attachments. The standards are required by the Health Insurance Portability and Accountability Act of 1996. They will be used to transmit clinical or administrative data for claims adjudication purposes	
Legal Deadline:			
Timetable:		NPRM Interim Final Rule	09/23/2005 TBD
Agency Contact : Elizabeth Holland, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, Mailstop S2-26-17, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-1309. Email : elizabeth.holland@cms.hhs.gov			
343.	Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies		
Legal Authority:		Sec. 4312(a) of BBA of 1997	
CFR Citation			
Abstract:		This rule implements section 4312(a) of the Balanced Budget Act of 1997, which requires a Medicare supplier of durable medical equipment (DME) to furnish CMS with a surety bond.	

Legal Deadline:			
Timetable:		NPRM NPRM Comment Period End Final Action	8/01/07 10/01/07 08/2010
Agency Contact : Frank Whelan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Mailstop C3-02-16, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-1302. Email : frank.whelan@cms.hhs.gov			
344.	Revisions to Payment Policies Under the Physician Fee Schedule for CY 2009		
Legal Authority:		Social Security Act, sec. 1102; Social Security Act, sec 1871	
CFR Citation			
Abstract:		The major rule makes changes affecting Medicare Part B payment to physicians and other Part B suppliers	
Legal Deadline:			
Timetable:		NPRM NPRM Comment Period End	7/7/08 8/29/08
Agency Contact : Diane Milstead, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Mailstop C4-03-06, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-3355. Email : diane.milstead@cms.hhs.gov			
345.	Changes to Long Term Care Prospective Payment System Based on Specific Provisions in SCHIP Extension Act of 2007		
Legal Authority:		Provisions on sec. 114 of PL 110-173 (MMSE Act of 2007); sec 1886(d) of the Social Security Act as amended by sec 114 of PL 110-173 (MMSE Act of 2007)	
CFR Citation			
Abstract:		This rule implements provisions of the Medicare, Medicaid and SCHIP Extension Act of 2007 relating to long-term care hospitals. In addition to amending section 1861 of the Act with a new definition of LTCHs, this rule includes provisions that are effective on the date of enactment (December 29, 2007). Specifically, the statute imposes a 3-year delay in implementation of certain payment policies that set percentage threshold for LTCH patients admitted from certain referring hospitals and raises the percentage threshold for those LTCHs unaffected by the 3-year delay. The legislation imposes the same 3-year delay on the implementation of a particular payment adjustment for short-stay patients and also for the possible application of a one-time adjustment to the standard Federal rate. The statute also required a change in the Federal rate for FY 2008, (effective April 1, 2008). Additionally, the statute created a 3-year moratorium on the establishment of new LTCHs and LTCH satellites and on bed expansion in existing LTCHs, subject to significant exceptions.	
Legal Deadline:			
Timetable:		Interim Final Rule Interim Final Rule Final Action	5/6/08 5/22/08 5/00/08
Agency Contact : Tzvi Hefter, Director, Division of Acute Care & Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Mailstop C4-08-06, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-4487. Email : tzvi.hefter@cms.hhs.gov			
346.	Medicare and Medicaid Programs: Hospice Care Conditions of Participation		
Legal Authority:		42 USC 1302; 42 USC 1395hh	
CFR Citation			
Abstract:		This final rule is a regulatory reform initiative that revises existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, and allow hospices greater flexibility in meeting quality standards. These	

		changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.		
Legal Deadline:				
Timetable:		NPRM Final Action	5/27/05 6/5/2008	
Agency Contacts: Mary Rossi-Coajou, Health Insurance Specialist, Department of Health and Human Services, Clinical Standards Group, Mailstop S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244. Phone : 410-786-6051. Email : mary.rossicoajou@cms.hhs.gov . Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Clinical Standards Group, Mailstop S3-02-01, 7500 Security Boulevard, MD 21244. Phone : 410-786-6617. Email : danielle.shearer@cms.hhs.gov				
347.	Inpatient Psychiatric Facility Prospective Payment System – Update for Rate Year Beginning July 1, 2008			
Legal Authority:		PL 106-113, sec 124 BBRA		
CFR Citation				
Abstract:		This notice updates the Inpatient Psychiatric Facility Prospective Payment System for rate year (RY) 2009.		
Legal Deadline:				
Timetable:		Completed	5/7/08	
Agency Contact : Janet Samen. Phone : 410-786-4533. Email : janet.samen@cms.hhs.gov				
348.	Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates			
Legal Authority:		sec. 123 PL 106-113; sec 307(b) PL 106-554; sec 114 of PL 110-173		
CFR Citation				
Abstract:		This major rule finalizes changes to the Medicare long-term care hospitals (LTCH) prospective payment rates for rate year (RY) 2009.		
Legal Deadline:				
Timetable:		Completed	5/9/08	
Agency Contact : Michele Hudson. Phone : 410-786-5490. Email : michele.hudson@cms.hhs.gov				
349.	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities – Update for FY 2009.			
Legal Authority:		Social Security Act, sec 1886(e)		
CFR Citation				
Abstract:		This major rule updates the payment rates used under the Skilled Nursing Facilities Prospective Payment System beginning October 1, 2008.		
Legal Deadline:				
Timetable:		Completed NPRM Final Action	5/7/08 8/8/08	
Agency Contact : Bill Ullman. Phone : 410-786-5667. Email : bill.ullman@cms.hhs.gov				
350.	Hospice Wage Index for FY 2009			
Legal Authority:		42 USC 1814(i)(1) and 1814(i)(2)		
CFR Citation				
Abstract:		This rule updates the annual hospice wage index for FY 2009. The wage index is used to reflect local differences in wage levels.		
Legal Deadline:				
Timetable:		NRPM Final Action	5/1/2008 8/8/08	
Agency Contact : Terri Deutsch. Phone : 410-786-9462. Email : terri.deutsch@cms.hhs.gov				