

## A.3 Agency-Specific Initiatives

CFR Cite	Reference	Agency	Purpose	Impact
<b>FDA Medical Products</b>				
21 CFR 803	Electronic Medical Device Reporting	FDA/CDRH	Would convert adverse events reporting of medical devices to a paperless system.	Would allow paperless reporting of adverse events
21 CFR	Down-classifications of Medical Devices (various)	FDA/CDRH	Review classifications of medical devices to determine if down-classification (i.e., move to a classification with less stringent requirements) is appropriate.	Regulate based on risks and reduce regulatory burden.
21 CFR 814	Revision of Device Premarket Approval Regulations (21 CFR 814.39); Special PMA Supplement Changes Being Effected	FDA/CDRH	Remove duplicative requirements	Streamline and clarify regulatory requirements.
21 CFR 882	Revise 21 CFR 882.5975 referencing device classification for dura mater, now regulated as an HCT/P	FDA/CDRH	Clarify classification of dura mater.	Clarification of regulatory status
21 CFR 351 21 CFR 360 21 CFR 371	General Hospital and Personal Use Devices; Issuance of Draft Special Controls for Infusion Pumps	FDA/CDRH	Based on an analysis of death and serious injury reports submitted to FDA, the agency is establishing special controls to provide reasonable assurance of safety and effectiveness of these devices.	Increased safety for patients.
21 CFR 801	Use of Symbols in Device Labeling	FDA/CDRH	Allow validated symbols in certain device labeling without the need for accompanying English text.	Reduce burden of labeling requirements by permitting harmonization with labeling for international markets
21 CFR 10 21 CFR 314 21 CFR 600 21 CFR 601 21 CFR 606	Postmarketing Safety Reporting Requirements for Human Drugs and Biological Products	FDA/CDER	FDA is revising certain definitions and reporting requirements based on recommendations of the ICH.	Revise reporting requirements and times to enhance the quality of safety reports received by FDA.
21 CFR 201 21 CFR 606	Bar Code Rule for Drugs	FDA/CDER & CBER	FDA is conducting a retrospective economic review of an economically significant regulation.	Assess costs and benefits to determine if rule should be modified to take into account changes in technology that have occurred since the rule went into effect.
21 CFR 210 21 CFR 211	Amendment to CGMP regulations for Finished Pharmaceuticals (Pharmaceutical CGMP for the 21st Century--Phase 2)	FDA/CDER	FDA is revising its CGMP regulations to accommodate advances in technology and to harmonize with the other International standards.	Flexibility and harmonization for pharmaceutical industry.
21 CFR 210 21 CFR 211	Amendment to CGMP regulations—Components	FDA/CDER	FDA is revising its CGMP regulations to address control of drug components.	Provide greater assurances of safety and quality and address some of the challenges of globalization of drug manufacturing.
21 CFR 314	Implementation of 505(q) – Amendment To Citizen Petitions, Petitions for Stay of Action and Submissions of Documents to Dockets	FDA/CDER	FDA is revising its existing regulations to implement provisions of the FDA Amendment Act.	Clarify certifications needed when filing petitions related to generic drug applications.
<b>FDA Foods</b>				
21 CFR 101	Food Labeling (Nutrition Initiative)	FDA/CFSAN	Revising and updating food labeling regulations to make nutrition information on packaged food label more useful to consumers.	Improving nutrition information will help consumers make better dietary choices.

21 CFR 110	Preventive Controls (Modernization of Current Food Good Manufacturing Practice Regulations)	FDA/CFSAN	In recognition that existing food GMP rules are inadequate, the Food Safety Modernization Act requires FDA to establish preventive controls for food facilities.	Reduced illness and death from food-borne illness.
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### CMS Conditions of Participation

42 CFR Part 484	Home Health Agency CoPs Proposed Rule	CMS	Remove unnecessary prescriptive and burdensome requirements to reflect current practice and streamline operations.	Increase the amount of time clinicians can spend with patients and lessen time on paperwork.
42 CFR Part 482	Hospital CoPs Proposed Rule	CMS	Remove or revise multiple requirements that are inconsistent with other requirements or impose unnecessary burdens to increase flexibility.	Target to publish the proposed rule is September. Estimated net savings to hospitals could reach at least \$600 million annually; \$3 billion over 5 years.
42 CFR 405	Proposed Rule for Non-Hospital Facilities on Provisions to Promote Program Efficiency, Transparency, and Burden Reduction	CMS	Revise or eliminate provisions affecting non-hospital providers that are unnecessary, obsolete, or excessively burdensome.	Target for publication is September 2011. Improved access to care, increased flexibility, better quality and lower costs. CMS estimates the net savings to End Stage Renal Disease facilities, which will be affected most by these changes, could approach \$200 million in the aggregate.

### CMS Review of Appeals process and ALJ provisions

42 CFR 405.720 and 722	Reconsiderations and Appeals Under Medicare Part A; Hearing; right to hearing.	CMS/OS-OMHA	Clarify and streamline appeals procedures.	Eliminate confusion and unnecessary duplication.
42 CFR 405.855	Appeals Under the Medicare Part B Program; ALJ hearing	CMS/OS-OMHA	Clarify and streamline appeals procedures.	Eliminate confusion and unnecessary duplication.
42 CFR 422 and 423	Contract Year 2012 Part C & D Final Rule	CMS/OS-OMHA	Translating the marketing materials for plan sponsors will result in significant savings to plan sponsors. CMS estimates per contract savings to be \$15,200 for the first year of translation and \$750 for annual updates for each of 305 sponsor contracts. CMS is investigating translating other Part C and D materials into other languages, so that plans need not undertake the translation themselves.	CMS estimates that net savings to plan sponsors could be as high as \$4.6 million for 2012 and \$230,000 for subsequent years.
42 CFR Part 498	Appeals Procedures for Determinations that Affect Participation in the Medicare Program and for Determinations that Affect the Participation of ICFs/MRs and Certain NFs in the Medicaid Program	DAB	Remove references to determinations by OIG because superseded by 42 CFR Part 1005	Eliminate confusion
42 CFR 430.2; 42 CFR 457.230; 45 CFR 1355.30(c)	Other applicable Federal regulations; FFP for State ADP expenditures; Other applicable regulations.	DAB	Remove outdated references to 45 CFR Part 74 to make regulations consistent with 2003 changes. Public assistance grants to states are now subject to 45 CFR Part 92. See 68 Fed. Reg. 52844 (Sep. 9, 2003).	Avoid disputes about what requirements apply

42 CFR Part 498.83(d)	Departmental Appeals Board action on request for review.	DAB	Remove outdated reference to Public Health Service and revise to state that "review will be conducted by a panel of at least <i>three</i> members of the Board, designated by the Chair or Deputy Chair," as intended.	Avoid confusion and possible procedural challenge
Various provisions under Titles 42 and 45 of CFR (e.g., 42 CFR 457.206©)	Administrative appeals under SCHIP.	DAB	Remove outdated references to "Departmental Grant Appeals Board" and replace with "Departmental Appeals Board"	Eliminate confusion
42 CFR Part, 488 Subpart C	Survey Forms and Procedures	DAB	Superseded by 42 CFR Part 488, Subpart E	Eliminate confusion