

A.4 Other Reviews Consistent with 13563

CFR Cite	Reference	Agency	Purpose	Impact
Reconsideration of Need for Final Rule consistent with 13563				
RIN 0920-AA31	Possession, Use, and Transfers of Select Agents and Toxins (SARS-Cov and Chapare Virus)	CDC	Will merge with Biennial Review of List of Select Agents and Toxins (RIN 0920-AA34).	More efficient rulemaking
RIN 0920-AA04	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	CDC	Review of comments to the NPRM indicates that additional analysis is needed to assess the economic impact of its proposed rule. CDC plans to withdraw the proposed rule and consider possible alternative approaches	Existing regulations will enforce quality assurance and administrative provisions while it explores alternative approaches.
RIN 0920-AA36	Amendments To Establish Wildland Firefighting Protection Performance Requirements for Approval of Respiratory Protective Devices	CDC	Respiratory Protection requirements were established in a national consensus standard, NFPA 1984, published March 2011. This NFPA standard requires NIOSH certification for respirators fulfilling the requirements of the standard.	NIOSH is considering the possibility of not publishing this Final Rule. Instead NIOSH will rely on the NFPA standard (which requires NIOSH certification) as it provides expected levels of respiratory protection.
Increasing Transparency consistent with 13563				
42 CFR 422 and 423	Contract Year 2012 Part C & D Final Rule	CMS	CMS began annual rulemaking to promote transparency, enhance beneficiary protections, fine-tune policy, improve CMS oversight of its contracts, and eliminate duplicative and outdated regulations. Both the industry and the advocacy community have been supportive of annual rulemaking as a way of increasing transparency in CMS' policy development process. The industry wants the annual regulations published as early as possible in the year to allow maximum time to implement policy changes prior to the bid submission deadline for the following contract year (first Monday in June).	Increase transparency
42 CFR Part 441	Home and Community Based Services Waivers	CMS	The provision is unnecessary or obsolete because it hinders State Medicaid programs from designing waivers based on functional need and prevents States from consolidating waiver services to multiple target groups. The consolidation of waivers reduces the administrative costs to States for management and oversight, and potentially offers a better tool for State allocation of scarce resources across multiple target populations.	Reduced administrative burdens and costs to states and better tools for states to use in administering the program.
45 CFR 60 and 61	Merger of the National Practitioner Data Bank for Physicians and Other Health Care Practitioners with the Healthcare Integrity and Protection Data Bank (HIPDB) for Final Adverse Information on Health Care Practitioners, Providers and Suppliers	OIG/HRSA	Section 6403 of Affordable Care Act merges the HIPDB into the National Practitioner Data Bank (NPDB), thereby eliminating the need for 45 CFR 61	Merging the Data Banks reduces burdens on users by eliminating the need for users to follow two different regulations and pay two separate fees to obtain information; Eliminates OIG and DOJ oversight of the HIPDB.

Other Activities consistent with 13563

42 CFR Part 412	Inpatient Rehabilitation Facility Prospective Payment System Final Rule	CMS	Removes outdated and unnecessary requirements, including change in ownership regulations and mergers and acquisitions. This action will help CMS better meet changing patterns of demand for IRF services. CMS gets numerous questions from providers regarding the interpretation of these requirements because they are difficult to interpret and are repetitive. CMS also believes that these requirements are outdated and are no longer necessary.	Published July 29, 2011. Expected to reduce burden and increase flexibility.
21 CFR 606 21 CFR 630	General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification	FDA/CBER	FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.	Fulfill requirements of Regulatory Flexibility Act.
21 CFR 203 21 CFR 205	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures	FDA/CDER	FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.	Fulfill requirements of Regulatory Flexibility Act.
21 CFR 1002 21 CFR 1010 21 CFR 1040	Laser Products; Amendment to Performance Standards	FDA/CDRH	Amending the performance standards for laser products to achieve closer harmonization with the International Electrotechnical Commission (IEC) standards.	Would harmonize more closely with the IEC and reflect current advances in science.
21 CFR 203 21 CFR 205	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures	FDA/CDER	FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.	Fulfill requirements of Regulatory Flexibility Act.
45 CFR 61	Healthcare Integrity and Protection Data Bank (HIPDB) for Final Adverse Information on Health Care Practitioners, Providers and Suppliers	HRSA	Section 6403 of Affordable Care Act merges the HIPDB into the National Practitioner Data Bank (NPDB), thereby eliminating the need for 45 CFR 61	Cost savings for organizations and practitioners who have the authority to obtain HIPDB; Time saving for reporters and queries of the Data Bank information; Eliminates OIG and DOJ administration of the HIPDB.
31 CFR Part 33 and 45 CFR Part 155	State Innovation Waivers under Section 1332 of the Affordable Care Act	CMS (with Treasury)	HHS and Treasury jointly-issued a proposed rule allowing States to apply for a waiver of certain statutory requirements of the Affordable Care Act. The waivers will be known as State Innovation Waivers and would promote state flexibility in designing "health care solutions that work best for them." This effort is consistent with E.O. 13563.	Increase flexibility for States.

Other CMS Rules under Review

42 CFR Part 416	Ambulatory Surgical Centers (ASC) Conditions for Coverage: Same-Day Services Final Rule	CMS	Reduce burden on ASCs and improve timeliness in access to care by allowing patients' rights information to be given on the day of the services.	\$50 million in savings annually--Savings in patient time of \$35 million; \$17.5 million in savings for providers.
42 CFR Part 418	Hospice Wage Index PPS Final Rule	CMS	The current requirement states that the physician who conducts the face-to-face visit with a Medicare hospice patient prior to recertification must be the same physician who completes the recertification. This may risk access to care for patients in areas of physician shortages, and is burdensome for hospices to implement, given the difficulty some	Published on July 29, 2011. Expected to increase flexibility and reduce burdens on hospice services and physicians.

			hospices have in obtaining physician resources.	
42 CFR Part 416	Physician Fee Proposed Rule	CMS	Remove the new lab signature requirement that the physician sign orders for a clinical lab test. Reduces burden by eliminating unnecessary documentation. The physician, clinical laboratory, and nursing home community perceive the existing requirement to be a significant additional burden; and the clinical laboratory industry believes they will not be paid for many laboratory tests because they do not anticipate full compliance.	Published July 19, 2011. Expected to reduce burdens and increase flexibility.
42 CFR Part 440	Home Health Face-to-Face Requirement	CMS	Align this requirement for Medicaid with the existing requirement for Medicare that physicians document a face-to-face encounter with the Medicaid beneficiary within certain timeframes.	Published July 12, 2011. Expected to reduce unnecessary burdens of two different requirements. CMS's Office of the Actuary estimates that the net savings from this change will result in savings to Medicare of roughly \$870 million over ten years.

Other FDA Rules under Review

21 CFR 558	Veterinary Feed Directives	FDA/CVM	Improve efficiency of the process for veterinarians to issue feed directives.	Streamlined VFDs will assist veterinarians and medicated feed manufacturers.
21 CFR 514 21 CFR 510	New Animal Drugs—Records and Reports concerning experience with approved drugs and medicated feeds	FDA/CVM	Reviewing regulations to determine how to clarify, streamline, and harmonize.	Aligning with international standards and clarifying requirements will result in improved reporting by sponsors.
21 CFR 58	Good Laboratory Practice for Nonclinical Investigations	FDA/OC	Review standards for nonclinical investigations to determine how best to update them.	Update standards for nonclinical investigations.