

May 28, 2002

Mr. John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building, Rm. 10235
725 17th Street, NW
Washington, DC 20503

Re: Comments on the OMB Draft Report to Congress on the Costs and Benefits
of Federal Regulation, 67 Fed. Reg. 15014

Dear Mr. Morrall:

The Office of Advocacy of the U.S. Small Business Administration (SBA) was established by Congress pursuant to Pub. L. No. 94-305 to advocate the views of small business before Federal agencies and Congress. Among its primary statutory mandates is the requirement to measure the direct costs and other effects of government regulation on small businesses, and make legislative and non-legislative proposals for eliminating excessive or unnecessary regulations on small businesses.¹ In addition, the Chief Counsel of Advocacy is required by section 612(a) of the Regulatory Flexibility Act (RFA)² to monitor agency compliance with the RFA. The RFA requires Federal agencies to consider the impacts of their regulatory proposals on small entities, and determine whether there are equally effective alternatives that would reduce the regulatory burden on small entities.

Advocacy is pleased to be able to respond to OMB's request for recommendations for the reform of Federal rules and guidance documents. In addition to the evaluation criteria suggested by OMB,³ the regulations and guidance documents listed below were also selected based on their relative and/or disproportionate impact on small entities.

Commercial Mail Receiving Agencies

Agency: United States Postal Service (USPS)

¹ 15 U.S.C. § 634b(3).

² 5 U.S.C. § 601 et seq.

³ OMB requested that commenters, when selecting rules for review, consider the following: whether the rule or program can be revised to be more efficient or effective; whether the agency has the statutory discretion to modify the rule or program; and whether the rule or program is important relative to the other rules or programs being considered for review. 67 Fed. Reg. at 15034.

Citation: Final Rule, 65 Fed. Reg. 49917 (August 6, 2000); 39 CFR part 111

Authority: 39 U.S.C. §§ 101, 401, 403, 404, 3001-3011, 3201-36621, 5001

Problem: The final rule requires all Commercial Mail Receiving Agency (CMRA) users to use either "PMB" (private mailbox) or "#" in their addresses rather than the terms apt., suite, unit, etc. USPS asserted that the designation was necessary to deter fraud by ensuring that the public would be aware of a business' true address identity. There was no indication that fraudulent activity occurred at any greater rate at CMRAs than USPS mailbox facilities, or that the particular requirement would in any way deter fraud. The rule requires small businesses to change all of their business materials to reflect that they were using a CMRA. In addition to the change being costly, it also places a stigma on small businesses that use CMRAs for a business address—especially legitimate home-based businesses. The agency received 8,000 comments in opposition and 10 comments in support of the regulation.

Moreover, on April 9, 2001, the USPS Office of Inspector General (OIG) issued a report on USPS's rulemaking process in the CMRA rule. The OIG found that USPS did not "demonstrate the need for regulatory change by presenting statistical or scientific data to support claims of mail fraud conducted through private mailboxes." Moreover, the regulations "did not show how the regulations would curb fraud, assess the impact of the proposed rules on receiving agencies and private boxholders, or consider alternatives to revising the rules." The OIG also found that the rules represented significant changes that could cost receiving agencies and their customers millions of dollars.

Even though the OIG found that the regulation was problematic, on November 14, 2001, USPS amended the CMRA rule to provide procedures to identify when an office business center (OBC) or part of its operation is considered a CMRA for postal purposes. OBCs provide private office space for customers along with other business support services. However, some OBCs have customers who do not rent private office space, but only use the OBC for mail receipt (and sometimes other business support services as well). These customers may rent meeting rooms or offices from the OBC on an as-needed basis. Other customers may rent private office space on a part-time basis. The November 14th amendment made some OBC customers subject to the address requirements of the CMRA regulation.

Finally, the regulation may be in contravention of 39 U.S.C. § 403(c), which bars USPS from discriminating among users of the mails. Since small businesses, as opposed to large businesses, are the primary users of CMRAs, this regulation discriminates against small businesses.

This regulatory action is not subject to the notice and comment procedures of the Administrative Procedure Act, therefore, it is not subject to the RFA either. However, this is clearly a case where an independent agency of the executive branch is imposing costly requirements on large number of small businesses without adequate justification.

Solution: Rescind the regulation.

Impacts: It is nearly impossible to place a value on lost business or other effects that might be related to the stigma associated with complying with the requirements of the regulation. Moreover, the agency never calculated costs and benefits or the number of entities that would be affected when the regulation was proposed.

Sling Standard

Agency: Department of Labor, Occupational Safety and Health Administration

Citation: Final rule, (March 1976); 29 C.F.R. Part 1910.184

Authority: 29 U.S.C. § 655(b)(1) - (5)

Problem: This rule sets safety requirements in the use of slings to lift, hoist and load heavy items. The regulation affects construction firms, but has a disproportionate impact on small firms. The current standard is nearly 30 years old and does not address current industry practices and safety standards. OSHA's sling standard is in conflict with the consensus standard B30.9. This consensus standard was promulgated by the American Society of Mechanical Engineers and represents the current safety practices of the industry. OSHA has failed to issue an updated standard that is more realistic and practical for sling operations today.

Solution: Update the regulation to meet current industry standards.

Recordkeeping for Work-related Injuries, Illnesses and Fatalities

Agency: Department of Labor, Occupational Safety and Health Administration

Citation: Final rule, 66 Fed. Reg. 5916 (October 2001); 29 C.F.R. Part 1904

Authority: 29 U.S.C. § 655(b)(1)-(5); 29 U.S.C. 657(c)(1)-(3)

Problem: This rule requires employers to record and report work-related fatalities, injuries and illnesses. The definition of “work-relatedness,” the means by which a small employer will be able to determine the cause of an employee’s injury accurately, and whether it is recordable under OSHA’s new regulation (1904.5(a)) are problems that were communicated to OSHA when the rule was initially proposed, but are still in need of clarification since being finalized.

Solution: Rescind the regulation and work with industry to devise a clear and enforceable regulation.

Impacts: This rule would affect 1.4 million establishments, most of which are small.

General Operating and Flight Rules; Inspections

Agency: Department of Transportation, Federal Aviation Administration

Citation: Guidance; FAA Policy Order 8300.10, Chapter 83

Authority: 49 U.S.C. § 106 (g)

Problem: FAA’s guidance provides compliance assistance for its rules governing the maintenance, preventative maintenance, and alterations of U.S. registered civil aircraft operating within or outside of the United States (14 CFR Part 91.415). It is Advocacy’s concern that neither the rule’s provision for Approved Aircraft Inspection Programs (AAIP) nor the FAA internal Guidance on AAIP recognizes the advancements in FAA’s certification regulations (Part 21, 23, 25, etc.) The rule is over 30 years old and requires small operators to obtain FAA re-approval of their AAIPs for even minor technical changes. The requirements had greater validity 30 years ago when small turbine aircraft were first introduced. The guidance mandates thorough instructions in the ICA – Instructions for Continuous Airworthiness – that are in conflict with the approval process required by the regulation.

Advocacy is pleased that Appendix G to this rule (Reduced Vertical Separation Minimums) is being reviewed under section 610 of the RFA. The FAA has issued a Notice of Proposed Rulemaking on this Appendix to the rule; however, the guidance to Part 91.415 is in need of updating to current practices.

Solution: Update the guidance to reflect the approval process required by the regulation.

Impacts: Advocacy's data shows that there are a total of 2607 air transportation firms in the U.S. Of that number, approximately 95% are small businesses based on SBA's size standards. The administrative costs of reproduction and obtaining FAA approval are ongoing. FAA inspectors have used this provision to micromanage the program and to require inspections that are inconsistent with technological advances that have taken place in the industry.

Toxic Release Inventory (TRI)—Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Chemical Release Reporting

Agency: Environmental Protection Agency

Citation: Final Rule, 66 Fed. Reg. 4500 (January 17, 2001); 40 CFR Part 372

Authority: 42 U.S.C. §§ 11023, 11048; Section 313, Emergency Planning and Community Right to Know Act of 1986

Problem: This regulation treats lead as a persistent bioaccumulative toxic (PBT) pollutant. Treating lead as a PBT means that EPA considers lead to have higher adverse environmental effects than other types of chemicals; therefore, EPA has adopted a lower reporting threshold for PBTs. It is Advocacy's concern that characterizing lead as a PBT is not supported by scientific or cost/benefit analysis.

Solution: The agency should rescind the new requirement which would cause the reporting threshold to revert back to the statutory thresholds of 10,000-25,000 pounds.

Impacts: The cost of compliance to small firms is about \$100 million annually.

Toxic Release Inventory—Addition of Chemical and Petroleum Wholesalers to TRI Reporting; Community Right-to-Know Chemical Release Reporting

Agency: Environmental Protection Agency

Citation: Final Rule, 59 Fed. Reg. 61432 (November 30, 1994); 40 CFR Part 372

Authority: 42 U.S.C. §§ 11-13, 11028; Section 313 of the Emergency Planning and Community Right to Know Act of 1986

Problem: The emissions from chemical and petroleum wholesalers are insufficient to warrant reporting. The reported releases constitute less than 0.3% of the total for all affected industries. The reporting costs exceed the benefits

of reporting these de minimis values, and the reported emissions do not vary significantly from year to year.

Solution: The agency should delete these sectors from the reporting requirement, or change the reporting frequency to once every five years.

Impacts: Advocacy estimates that the impact of this reporting requirement to be as much as \$100 million.

Toxic Release Inventory—Alternate Threshold for Facilities with Low Annual Reportable Amounts; Community Right-to-Know Chemical Release Reporting

Agency: Environmental Protection Agency

Citation: Final Rule, 59 Fed. Reg. 38524 (July 28, 1994); 40 CFR Part 372

Authority: 42 U.S.C. § 6901 et seq.; Section 313 of the Emergency Planning and Community Right to Know Act of 1986

Problem: The short Form A, that provides significant savings to TRI long Form R filers, is only available to a fraction of those facilities who should qualify.

Solution: The short form should be tied to annual quantities of chemicals released to the environment, and not quantities recycled or waste burned for energy recover. In addition, the reportable quantity should be raised from 500 pounds to 5000 pounds because the lower threshold is too insignificant to be reported, and would be of no benefit to the affected communities.

Impacts: These changes would reduce paperwork for an additional 30,000 to 50,000 facilities.

Regulation of Hazardous Wastes

Agency: Environmental Protection Agency

Citation: 40 CFR Parts 261-268

Authority: Resource Conservation and Recovery Act (RCRA)

Problem: The agency has narrowly defined wastes to include materials that are not, in fact, wastes, but are materials that are destined for recycling or reuse. Thousands of small manufacturing businesses generate waste during the manufacturing process (e.g., recycled metals and solvents), and are affected by this regulation.

Solution: EPA should redefine waste materials to exclude recycled materials, which is consistent with the statute.

Impacts: Advocacy estimates that potentially hundreds of millions of dollars annually would be saved in complying with RCRA regulations.

Limited English Proficiency (LEP) Guidance

Agency: Health and Human Services, Office of Civil Rights

Citation: Notice of Republication of Policy Guidance, 67 Fed. Reg. 4968 (February 1, 2002)

Authority: Executive Order 13166 (Improving Access to Services for Persons with Limited English Proficiency)

Problem: The purpose of Executive Order 13166 is to clarify for recipients of federal funds, the steps that can be taken to avoid administering programs in a way that results in discrimination on the basis of national origin. To that end, the Executive Order requires each Federal agency providing federal financial assistance (in this case, Medicare/Medicaid reimbursements) to explain to recipients of federal funds their obligations under Title VI of the Civil Rights Act. HHS's guidance was born out of this general requirement. The guidance requires health care providers (receiving Medicare and Medicaid funds) to provide, on request, translation services to all patients with limited proficiency in the English language—including patients with private insurance and those who pay "out-of-pocket."

This policy could have a devastating effect on small healthcare providers, which could impact access to care for disadvantaged populations. The cost of complying with HHS regulations in general is already staggering, and forcing many providers to consolidate or go out of business. The additional cost of complying with the LEP guidance may force many others out of business, or at least force them to opt out of programs like Medicaid which serves disadvantaged individuals/communities.

The examples provided by HHS of how to comply with the guidance are either too expensive or unrealistic--ranging from contracting with a service for translation to soliciting community volunteers to provide translation. The guidance does not adequately take into account the resources available to a recipient of federal funds. In a memorandum to the heads of departments and agencies dated October 26, 2001, the

Department of Justice stated agencies should develop balancing factors in their guidance—including the resources available to a small business.

Solution: HHS should revise its guidance to reflect clearly that compliance with the guidelines may be waived if the translation requirements are impracticable based on resources or other balancing factors, consistent with Title IV.

Impacts: OMB’s March 14, 2002 report helps explain some of the likely costs associated with LEP in the healthcare industry. That report, titled, *Report to Congress; Assessment of the Total Benefits and Costs of Implementing Executive Order No. 13166: Improving Access to Services for Persons with Limited English Proficiency*, suggests the following costs: \$8.6 million for hospital emergency room visits, \$78.2 million for hospital inpatient visits, \$11.5 million for community health clinic outpatient visits, \$12.4 million of hospital outpatient visits, and \$156.9 million for private provider outpatient visits. The majority of the health care industry is comprised of small providers—either based on their status as a small business concern, or based on their non-profit status.

Hemp Food Products (Interpretation and Clarification of Listing Tetrahydrocannabinols in Schedule I)

Agency: Department of Justice, Drug Enforcement Administration

Citation: 66 Fed. Reg. 51530 (Interpretative rule), 66 Fed. Reg. 51535 (Proposed rule), 66 Fed. Reg. 51539 (Interim rule)—all published on October 9, 2002; 21 CFR Part 1308

Authority: 21 U.S.C. § 811, 812, 817(b); (Controlled Substances Act)

Problem: DEA issued an “interpretative rule” to interpret the Controlled Substances Act (CSA) and DEA regulations to declare any product containing any amount of tetrahydrocannabinols (THC) to be a schedule I controlled substance, even if the product is made from portions of the cannabis plant that are excluded from the CSA definition of “marihuana.” The proposed rule, issued simultaneously, revised the wording of DEA regulations to make clear that the listing of THC in schedule I refers to both natural and synthetic THC. Finally, the interim rule, also issued simultaneously, exempted industrial-use products such as soap, etc., as long as the products could not be absorbed into the human body.

The problem is that DEA never did an analysis of impacts on the long-existing hemp foods industry—an industry comprised entirely of small businesses that would now have to remove all its products from the shelves and cease manufacturing and selling the products. By labeling this

regulatory action as an “interpretation,” the agency was able to bypass notice and comment rulemaking and the requirements of the RFA. DEA simply ignored the substantive and administrative rights of the regulated community (which has been thriving for ten years) by re-interpreting a decades old statute and regulations. DEA refused to consider establishing guidelines to allow products that did not leave detectable traces of THC in the bloodstream.

Solution: The regulations should be rescinded.

Impacts: The entire hemp food industry would be eliminated. According to industry data, sales of hemp food products reached about \$5 million annually, but were growing.

Medicare and Medicaid Programs; Hospital Conditions of Participation; Patients’ Rights (1-hour Restraint Rule)

Agency: Health and Human Services, Centers for Medicare and Medicaid Services (formerly, the Health Care Financing Administration)

Citation: Interim Final Rule; 64 Fed. Reg. 36070 (July 2, 1999); 42 CFR Part 482

Authority: 42 U.S.C. § 1395bb, 1302, 1395hh; Social Security Act

Problem: CMS’s predecessor, HCFA, issued this interim final rule which contains standards for the use of patient restraints in hospitals. The one-hour restriction which is especially burdensome for small and rural hospitals because it requires treating physicians to make a face-to-face assessment of the patient within one hour of initiating restraint or seclusion. HCFA failed to analyze the impact of the one-hour provision in the rule and that no serious alternatives were considered. This particular question was adjudicated in the District Court of the District of Columbia, and the court agreed that the impact of the 1-hour provision had not been adequately considered. In September 2000, the court upheld the rule, but because the agency failed to comply with the RFA, the court remanded the rule back to the agency for the completion of a final regulatory flexibility analysis. Advocacy continues to insist that CMS complete the regulatory analysis as ordered by the court.

Solution: CMS should meet with industry groups and professional associations to devise a patient restraint standard that would meet the need for good patient care and provider resources. CMS should then re-publish the regulation with an appropriate standard.

Snowmobile Phase-out in Yellowstone Park, John D. Rockefeller, Jr. Parkway and Grand Teton National Park

Agency: Department of Interior, National Park Service

Citation: Final rule, 66 Fed. Reg. 7260 (January 22, 2001)

Authority: 16 U.S.C. § 1, 3, 9(a), 460(q), 462(k)

Problem: The National Park Service (NPS) published a final rule seeking to phase out snowmobile use in various national parks based on findings contained in a final environmental impact statement (FEIS). Small businesses represent 69 of 70 snowmobile dealers operating near the affected parks. However, the NPS erroneously certified that there would be no significant impact on a substantial number of small entities. The NPS did not adequately consider alternatives such as the use of new four-stroke snowmobile technology that was quieter and less polluting. Subsequently, the International Snowmobile Association and others sued the NPS. In a settlement agreement reached between the parties, the NPS agreed to obtain a supplemental environmental impact statement (SEIS). The SEIS was released on March 29, 2002.

Solution: NPS should withdraw the certification established in the FEIS and amend it in light of new information in the SEIS. If after reconsideration, the NPS finds that the rule will not be expected to have a significant economic impact on a substantial number of small entities, the Agency may certify the rule with a factual basis for the decision; otherwise, the NPS should prepare a final regulatory flexibility analysis (FFRA) and release it for public comment.

Impacts: In its cost-benefit analysis, NPS estimates that there are 69 rental firms in communities surrounding affected national parks which meet SBA's definition of small business (<\$5 million in annual receipts) and 5 which do not. Seventy of these rent snowmobiles and total lost revenue is estimated to be \$3.9 million. Thus, the cost per firm is \$56,000 (\$3.9 million/70). Thus, small businesses incur approximately 90 percent of compliance costs (69 x 56,000/74 x 56,000). NPS also provides the firm distribution by revenue: 31 have less than \$500,000, 17 with \$0.5-1 million, 14 with \$1-2.5 million, 7 with \$2.5-5 million, 4 with \$5-10 million, and 1 with \$10-20 million. Assuming each firm produces the maximum per category (e.g., 31 produce \$500,000, 17 with \$1 million, etc.), Advocacy finds that small businesses produce 60% of revenue generated by the local rental firms: $([31 \times \$500,000 + \dots + 7 \times \$5\text{million}] / [31 \times \$500,000 + \dots + 1 \times \$20\text{million}])$.

NPS also reports that, in greater Yellowstone, of the snowmobile, ski, and snowmobile rental firms, 31 have less than \$500,000 in annual revenue and 1 has \$10-\$20 million. The NPS states that the upper quartile profit-to-revenue ratio for the recreation industry (SIC 7999) is 14.2%. If we assume, conservatively, that the 31 small firms rent snowmobiles and each produces \$500,000 in annual sales, the per-firm profits would be \$71,000 ($0.142 \times \$500,000$). Using the same logic, the profit of the large firm would be \$2.8 million ($0.142 \times \20 million). The NPS estimates that the cost per firm would be \$56,000 annually. Then, respectively, cost per profit-dollar would be 78% ($56,000/71,000$) and 2% ($56,000/2.8 \text{ million}$).

Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Unites Under the Physician Fee Schedule for Calendar Year 2002

Agency: Health and Human Services, Centers for Medicare and Medicaid Services

Citation: Final rule, 66 Fed. Reg. 55245 (June 4, 1997); 42 CFR Part 45

Authority: 42 U.S.C. § 1848(c) (Social Security Act)

Problem: This regulation adjusts the fee schedule for services provided primarily by physicians. Portable x-ray and EKG providers, non-physician groups, are included in this fee schedule. The agency, by all accounts, adopted a one-size-fits-all regulation that affects small providers disproportionately. The agency failed to assess adequately the true operating costs of the portable x-ray and EKG provider industry in its consideration of the regulatory flexibility analysis required by the RFA. By failing to do this, a serious economic hardship was placed on portable x-ray and EKG providers.

The portable x-ray and EKG industry is a relatively small industry that provides an invaluable public service to Medicare beneficiaries. Rather than transport an elderly patient from a nursing home to a hospital for ordinary x-rays, the portable x-ray providers bring the equipment to the patient and provide the results to the nursing home. This is far less expensive and far less traumatic for frail and elderly patients. No public good is achieved by forcing the providers out of business.

Solution: The agency has pledged to take the first step by allowing portable x-ray and EKG providers to join the board that issues recommendations to CMS. However, additional changes to the methodology for updating physician fees are warranted such as replacing the sustainable growth rate (SGR) system with a system that tracks practice costs more accurately. This would go far in helping CMS conduct legitimate analyses on how their regulations affect small business.

Certificates of Medical Necessity

- Agency:* Health and Human Services, Centers for Medicare and Medicaid Services
- Authority:* 42 U.S.C. § 1395m(j)(2)
- Problem:* Physicians, the vast majority of which are small, under Medicare regulations, must supply certificates of medical necessity (CMNs) for items of durable medical equipment (DME), short-term nursing home rehabilitation, home health nursing visits, but also for pharmaceutical items such as diabetic supplies. The requirement that physicians accompany prescriptions with certificates of medical necessity is unnecessary and duplicative. The prescription itself should be adequate to certify the medical need of items like monitors, syringes, test strips, etc.
- Solution:* Modify Medicare regulations to eliminate CMNs where a prescription is adequate.

Monthly Versus Semi-Monthly Federal Employment Tax Deposits

- Agency:* Internal Revenue Service
- Citation:* 26 CFR § 31.6302.1
- Authority:* Internal Revenue Code Sections 3102 and 6302(g)
- Problem:* An employer that meets the threshold tests and for the first time, reports more than \$50,000 in aggregate employment taxes, must change from the previous payment schedule of paying on the 15th of the month following the pay date (the schedule when the aggregate was less than \$50,000) to paying on the third business day after the pay date. This is a drastic transition for small business owners who find themselves suddenly owing in 3 days what they had previously owed in 30 or 45. It causes serious cash flow problems to small business owners who have not had to cope with this problem. Also, this amount has not been adjusted for inflation.
- Solution:* Raise the monthly payment threshold to \$100,000 to keep pace with inflation.
- Impacts:* Changing the threshold shifts the burden of cash-flow away from the smallest businesses to a level of business that was contemplated when the \$50,000 was first set. The problem is one of timing only, which makes very little difference to the federal government, but can make all the difference to the successful operation of a small business.

Partnership Investments in Qualified Small Business Stock

Agency: Internal Revenue Service

Authority: 26 USC §1202; 26 USC §1045

Problem: Investment Partnerships which would be most likely to use the provisions of Internal Revenue Code section 1202 and section 1045 are hamstrung by the fact that the IRS has not modified its regulations to explain how section 1045 would apply to partnerships that disposes of one qualified small business stock and reinvests in another qualified small business stock. Section 1045 allows taxpayers, other than corporations that dispose of Qualified Small Business Stock (QSBS) (as defined in section 1202) held more than six months, to defer tax on the sale of those assets if they invest the proceeds in other QSBS under certain circumstances.

Unfortunately, Section 1045 is silent (and the Treasury Department has issued no guidance) regarding how partners can obtain rollover benefits in the context of a variety of very common transactions involving partnerships. For example, virtually all venture managers and most venture investors hold partnership interests in a number of venture capital partnerships. No guidance is available, however, with regard to how a partner's share of gains attributable to one partnership's disposition of QSBS can be rolled over if another partnership, to which that partner has contributed capital, makes a timely investment in other QSBS.

Solution: IRS should amend the regulations connected with section 1202 and section 1045 to address the problem where a partnership is making the transaction so that the provisions will be usable in a fashion that Congress intended.

The Office of Advocacy appreciates the opportunity to comment. We look forward to working with you to help modify or rescind the regulations and guidance cited above. Making these changes will reduce unnecessary regulatory burden on small entities and improve small business confidence in the regulatory process. Please do not hesitate to contact me, or my Director of Interagency Affairs, Shawne McGibbon, at 202-205-65233.

Sincerely,

Thomas M. Sullivan
Chief Counsel for Advocacy

Shawne Carter McGibbon
Director of Interagency Affairs