



# Economic Impact Analysis of the Proposed Hospital Sterilizers Area Source Standard

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**Economic Impact Analysis of the Proposed Hospital Sterilizers Area Source Standard**

U.S. Environmental Protection Agency  
Office of Air Quality Planning and Standards  
Health and Environmental Impacts Division  
Air Benefits and Costs Group  
Research Triangle Park, NC

## **Hospital Sterilizers Area Source Proposed Rule – Economic Impact Analysis**

### **Background on Hospital Industry**

The portions of the hospital industry that are affected by this proposal are NAICS 62211 (General Medical and Surgical Hospitals) and NAICS 62231 (Specialty (Except Psychiatric and Substance Abuse) Hospitals).

This category potentially includes many types of hospitals such as academic medical center/university-based/teaching hospitals, community hospitals, specialty hospitals (i.e., orthopedic or pediatric), and tertiary care facilities that are qualified to handle major trauma cases (i.e., burns and catastrophic accidents). There are also distinctions between public and private hospitals, hospitals that are part of a healthcare system (i.e., organizations such as Kaiser Permanente), Veterans Administration hospitals, and other types of facilities.

The hospital industry impacts the lives of nearly every person in the United States. According to the 2002 Economic Census of the Health Care and Social Assistance Industry, which covers NAICS 62211 and 62231, there are 6,541 hospitals in the United States. These hospitals employ approximately 5.2 million people with an annual payroll of almost \$196 billion. Of these hospitals, 5,404 are classified in NAICS 62211 and 532 are classified in NAICS 62231.<sup>1</sup>

The revenue obtained by hospitals in NAICS 62211 in 2002, the latest year for which we have such data, is nearly \$481 billion while the revenue obtained by hospitals in NAICS 62231 in 2002 is about \$15 billion. Therefore, the average revenue for a hospital establishment (which is a facility, and not necessarily a parent firm or entity) in NAICS 62211 is \$89 million while the average revenue in NAICS 62231 is \$29 million. Revenue for each type of hospital is largely obtained from in-patient services (56.8 percent) and outpatient services (30.2 percent) in NAICS 62211 and breaks out very similarly for NAICS 62231 (57.6 percent and 20.2 percent, respectively).

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<sup>1</sup> U.S. Census Bureau. 2002 Economic Census, Health Care and Safety Administration Series. Report No. EC-02-621-02. Found on the Internet at <http://www.census.gov/econ/census02/guide/INDRPT62.HTM>.

There is not a great degree of concentration amongst firms in the hospital industry. According to the 2002 Economic Census, the 4 largest firms in NAICS 62211 own only 415 hospitals, or less than 8 percent of the establishments classified in this NAICS code, and the 50 largest firms own 1,220 hospitals, or only 23 percent of the establishments classified in this NAICS code. If one examines the amounts of revenue received by firms as a measure of firm concentration, the 4 largest firms in NAICS 62211 receive only 9.5 percent of all revenues earned by firms classified in this code while the 50 largest firms receive only 29.7 percent of all revenues. In NAICS 62231, there is a higher degree of firm concentration. The 4 largest firms own 28.2 percent of the hospitals classified in this NAICS code, while the 50 largest firms own 71 percent of the hospitals classified in this NAICS code.

This result may be somewhat surprising since there was a considerable degree of hospital consolidation in the U.S. during the late 1990's. One source claims as many as 900 mergers occurred from 1994-2000.<sup>2</sup> This surge in consolidation has led to concern about the effects on competition in local markets for hospital services. Federal antitrust enforcement agencies such as the Federal Trade Commission (FTC) along with the U.S. Department of Justice (DOJ) brought challenges against a number of hospitals seeking to merge. The courts, however, have ruled against the antitrust enforcement agencies on every hospital merger case tried in the last decade.<sup>3</sup>

Markets for the services provided by hospitals are local in nature due to the nature of the services involved.<sup>4</sup> This reflects the fact that consumers strongly prefer hospitals close to their homes. While the price elasticity of demand can be quite low for health care services as a whole (below -0.2), the price elasticity of demand for hospital services

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<sup>2</sup> Abraham, Jean, Gaynor, Martin, and Vogt, William. Entry and Competition in Local Hospital Markets. National Bureau of Economic Research. Working Paper 11649. Available on the Internet at <http://www.nber.org/papers/w11649>

<sup>3</sup> Reference 2.

<sup>4</sup> Frech, H.E. (1987). Comments on (hospital) antitrust issues. *Advances in Health Economics and Health Services Research*, 7:853-872.

can be quite large (nearly -6, or highly elastic).<sup>5</sup> Hence, those who go to hospitals do consider the price of services as a parameter for decision making.

Profit margins for hospitals range from 3 to 5% based on historical averages (historical median of 4.6% based on American Hospital Association data from 1990-2000). Hospitals reported an average profit margin of 5.2 percent in 2004, according to the American Hospital Association (USA Today, "Hospitals' Profit Margin Hits 6-year High in 2004, downloaded from the Internet on August 18, 2006). For-profit, publicly traded hospitals have profit margins in the high end of this range while the not-for-profit hospitals have profit margins closer to the low end. Typically, for-profit hospitals are larger than not-for-profit hospitals, and not-for-profit hospitals typically generate less revenue per bed than for-profit hospitals due to lack of economies of scale and larger overhead costs. For-profit publicly traded hospitals are 15% of facilities and about 13% of the beds available to incoming patients, and the remaining 85% of facilities (87% of beds) are not-for-profit.<sup>6</sup> Not-for-profit hospitals are exempt from federal tax; for-profit hospitals are not. In addition, smaller hospitals such as those in inner-city areas are likely to have lower profit margins than other urban hospitals.<sup>7</sup>

Economic growth in the hospital industry is expected to climb as the number of patients grow due to the aging of the U.S. population and the expansion of hospitals into outpatient care. One estimate projects hospital spending growth to average 6.2 percent annually between 2004 and 2014.<sup>8</sup> A major reason for this is an expected increase in Medicare hospital spending.

### **Affected Population of Hospitals**

Of 6,500 hospitals nationwide, roughly 1,800 sterilize with EO. It is estimated that 1,200 hospitals control EO emissions from sterilizers. Most hospitals that sterilize

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<sup>5</sup> Reference 2.

<sup>6</sup> Health Care Industry Market Update, Centers for Medicare and Medicaid Services. July 14, 2003.

<sup>7</sup> Issue Brief, National Health Policy Forum. March 1999.

<sup>8</sup> Heffler, Stephen. Smith, Sheila. Keehan, Sean. Borger, Christine. Clemens, M. Kent. and Truffer, Christopher. U.S. Health Spending Projections for 2004-2014. Health Tracking, February 23, 2005. Found on the Internet at <http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.74/DC1>.

with EO are located in urban areas (about 95%).<sup>9</sup> Based on a nationwide and State search for permits and inventory data, we specifically compared the number of hospitals identified and the number confirmed to conduct EO sterilization, and extrapolated to nationwide estimates. The percentage of hospitals with EO sterilization ranges from 28 to 33 percent. Based on this range, there are approximately 1,600 to 1,900 hospitals nationwide that conduct EO sterilization.

### **Control Devices to Reduce EO Emissions from Hospital Sterilizers**

The predominant type of air pollution control devices are the EtO-Abator<sup>TM</sup> and the Safe-Cell technology. Both technologies reduce emissions by approximately 99 percent. The EtO-Abator<sup>TM</sup> oxidizes the EO with a catalyst to form CO<sub>2</sub> and water vapor. The latest version of the EtO-Abator<sup>TM</sup> (sold by 3M) is sold only for use with pure EO systems; however, earlier versions were used with gas blends. The Safe-Cell technology, which can be used with either pure EO or EO gas blends, is a two-stage process. In the first stage, an acid hydrolysis scrubber removes EO from the gas stream and converts it to ethylene glycol (EG); in the second stage, the remaining EO is captured and destroyed on a dry bed filter impregnated with a chemical reactant.

Ethylene oxide emissions for hospital sterilizers have decreased over 90 percent (from 1,000 to 70 tons per year) from 1990 to 2005. We estimated that 1990 emissions levels of EO were 1,060 Megagrams (Mg)/yr (1,170 tons/year) from sterilization processes nationwide. In this study, all of the EO emissions were associated with area source facilities, i.e., there were no major source hospital facilities. Recently, industry representatives have cited declining trends in EO usage for sterilization processes. Nationwide EO usage in 2000 was estimated to be 192 Mg/yr (212 tpy). The nationwide EO usage in 2005 was estimated to be 122 Mg/yr (135 tpy). The decline in EO usage for hospital sterilization is due mainly to: (1) new regulations and excise taxes on chlorofluorocarbons (CFCs), (2) development of new sterilization processes, such as liquid peracetic acid and hydrogen peroxide plasma processes, for certain medical items, (3) increased concern over the toxicity of ethylene oxide residuals, and (4) new

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<sup>9</sup> Ec/R. EO Sterilizers Report. Prepared for the U.S. Environmental Protection Agency. December 2003.

restrictions on reprocessing single use devices (SUDs). As a corollary to the decline in EO usage and emissions, the number of hospitals that conduct EO sterilization has been declining. With the trends mentioned, hospitals in urban areas have begun to consolidate EO sterilization processes, and one hospital with a large sterilizer may conduct sterilization processes for its neighbor or affiliated hospitals or those in close proximity. In addition, regulation of EO sterilization at hospitals has contributed to the decline in the number of hospitals that conduct sterilization processes. In California, there were approximately 600 hospitals that operated EO sterilizers in 1991. Since implementation of the CARB regulation for hospital sterilizers in 1991, at least 60 percent of these hospitals are no longer conducting sterilization operations. In 2000, the Food and Drug Administration (FDA) regulated the reprocessing of SUDs, and these regulations have made it more difficult for hospitals to continue the reprocessing. Many hospitals have reacted to the 2000 FDA regulations by discontinuing the reuse of SUDs or by outsourcing the sterilization processing of SUDs. As a result of the many SUD reuse issues, when hospitals are outsourcing and using reprocessed devices, EO usage by contract sterilizers is increasing, and when hospitals are not reprocessing SUDs, EO usage by medical device manufacturers has increased as they manufacture more SUDs. Sterilization processes by commercial sterilizers, which include commercial contract sterilizers and medical device manufacturers, are subject to MACT controls under 40 CFR part 63, subpart O.

Emissions from controlled hospital sterilizers are negligible and we are not aware of any practical emission reduction strategies after control. Emissions from uncontrolled hospitals range from less than 10 to 17,800 lbs of ethylene oxide per year. The capital costs of add-on-controls for these facilities range from \$23,000 to \$130,000 per hospital. These costs do not include recordkeeping and reporting, monitoring, or testing costs; annualized costs of add-on-controls range from \$10,000 to \$46,000 per year in 2002 dollars. Any recordkeeping and reporting, monitoring, or testing costs are expected to be minimal.

### **Description of Proposed Rule**

Given the minimal EO emissions from this source category, the proposed rule does not include additional emission controls. The proposal rule includes a management practice to reduce EO emissions from hospital sterilizers that do not use control devices for such emissions. This practice consists of sterilizing full loads of items having a common aeration time. Facilities complying with this proposed rule by applying the management practice will be required to maintain records on-site of the date and time of sterilization and whether a full load was sterilized, and the reason for not running a full load. Finally, the proposal requires hospitals with controlled sterilizers to certify that the control devices are operating and will continue to operate in accordance with applicable State and/or local laws or, if controls are voluntary, in accordance with manufacturer's specifications.

The management practice will increase the awareness of pollution prevention and has the potential to reduce emissions from uncontrolled hospital sterilizers. The cost of this practice applied to uncontrolled hospital sterilizers nationwide is \$1.3 million (2005 dollars), and this cost may be off-set by the reduced purchasing costs of ethylene oxide and other operating costs resulting from fewer loads. These costs are calculated based on the 2005 estimate of 135 tpy EO nationwide.<sup>10</sup>

### **Results of Economic Impact Analysis**

The economic impacts of the proposed option are minimal. Of the 26 entities identified as owning 32 hospitals affected by this proposed option according to our databases, there are no affected entities with annualized compliance costs of greater than 0.1 percent of sales except for 1 small firm. We extrapolate the impacts to the universe of hospitals affected by this proposal, which is 630 hospitals owned by 512 entities, and

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<sup>10</sup> Research Triangle Institute. "Documentation of Emissions Control Cost Estimates and Nationwide Costs for Ethylene Oxide Sterilizers and Hospitals," March 13, 2006. Prepared for the U.S. Environmental Protection Agency.



the economic impacts are therefore no affected entities with annualized compliance costs greater than 0.1 percent of sales except for 1 small entity. Consequently, the impacts of this proposed option on the profits of these hospitals and output of their services are minimal. Impacts to the consumers of these services (primarily hospital patients) should be minimal as well using costs as a percent of sales as a proxy for the price increase that may result. While we have hospital industry-level data for 2002 only, we have revenue data for individually affected entities for 2005 in many instances. These data are taken from D&B, financial reports on hospital made available by various States, and other sources. Our dataset of 23 entities that own 32 affected hospitals are those entities for which we are fairly certain that the proposed rule will have an impact on them. We believe this data is representative of the impacts of this proposal on the 630 hospitals expected to be impacted by this proposal. The impacts are summarized in Table 1 below. Impacts for each affected firm and hospital facility can be found in the Appendix. Economic impact data for each affected hospital can be found in the file “EconomicImpactsHospitalSterlizersproposaldata.xls” which can be found in the public docket, and revenue data used in this analysis can be found in “Hospital\_Entity\_Revenue\_Data.xls” which is also in the public docket.

### **Results of Small Entity Analysis**

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. This analysis identified the businesses that will be affected by this proposed rule and provides an analysis to assist in determining whether this rule is likely to impose a significant economic impact on a substantial number of small businesses. The screening analysis employed here is a “sales test” that computes the annualized compliance costs as a share of sales for each company or affected entity.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) a small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; which for today's rule is a small parent company is less than \$31.5 million in gross revenue (NAICS 62211 and NAICS 62311);<sup>11</sup> (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impact of today's proposed action on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities (SISNOSE). This action proposes work practices to minimize the operation of the ethylene oxide sterilization unit and will therefore have minimal nationwide costs, i.e., less than \$2 million per year. We have determined that less than 3 percent of the hospitals are small entities as defined by the SBA. While we do not have any small entities identified in the dataset used for this rule's analyses, we do have some small entities identified as potentially affected but for which we do not have revenue data and thus cannot generate a specific impact estimate for them. We have also determined that none of these small businesses are significantly impacted by this proposal for none of them will incur annualized compliance costs of 0.1 percent of sales or greater. Based on this information on small business impacts, we make this certification.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

While we do not believe these options will lead to significant economic impacts on a substantial number of small entities, we have undertaken efforts to mitigate small entity impacts as part of this rulemaking. We continue to be interested in the potential impact of the proposed action on small entities and welcome comments on issues related to such impact.

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<sup>11</sup> The SBA small business size standards can be found at [www.sba.gov/size](http://www.sba.gov/size).

**Appendix – Detailed Results by Firm (or Entity) Affected by the Proposed Hospital Sterilizers Rule**

<b>Entity Name</b>	<b>Is Affected Entity Small According to SBA Definition?</b>	<b>Annualized Costs of Proposal for Affected Entity (2005 dollars)</b>	<b>Annualized Costs As a Percentage of Revenues for Affected Entity</b>
Resurrection Health Care Corporation	No	\$87,003	0.07
Victory Memorial Health Association	No	23,032	0.05
Bethesda Memorial Hospital, Inc.	No	20,657	0.01
Protestant Memorial Medical Center	No	13,014	0.007
Provena Hospitals	No	7,836	0.004
Bloomington Hospital, Inc.	No	9,535	0.003
Sparks Health System	No	8,939	0.004
North Shore Long Island Jewish Health System	No	10,131	0.003
Aléxian Brothers Medical Center, Inc.	No	7,869	0.003
Memorial Health System	No	11,156	0.002
JPS Health Network	No	5,438	0.002
Advocate Health	No	54,329	0.0018
Methodist Medical Center of Illinois	No	2,980	0.001
Rockford Health System	No	3,754	0.001
St. John's Hospital of the Hospital Sisters of the Third Order of St. Francis	No	3,003	0.0008
Elkhart General Hospital	No	2,682	0.0007
St. Vincent's Catholic Medical Centers of New York	No	3,650	0.0005
Charleston Area Medical Center (CAMC) System	No	2,047	0.0003
New York Health and Hospitals Corporation	No	10,166	0.0002

<b>Entity Name</b>	<b>Is Affected Entity Small According to SBA Definition?</b>	<b>Annualized Costs of Proposal for Affected Entity (2005 dollars)</b>	<b>Annualized Costs As a Percentage of Revenues for Affected Entity</b>
Adventist Health System Sunbelt Healthcare Corp.	No	4,338	0.0001
St. Francis Hospital and Health Centers	No	816	0.0001
Northwestern University Medical Center	No	2,684	0.0001
St. Mary's Good Samaritan Hospital	No	2,591	No impact estimate available due to lack of revenue data
US Federal Government	No	30	N/A

\* N/A – Not Applicable

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