DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Mammography Quality Standards Act; Amendments to Part 900 Regulations

Docket No. FDA-2013-N-0134

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many facilities that will be affected by this rule are defined as small businesses, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $150 million, using the most current (2017) Implicit Price Deflator for the Gross

Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

We invite comments on this Preliminary Regulatory Impact Analysis.

B. Summary of Benefits and Costs

The proposed rule would modernize mammography regulations by incorporating current science and mammography best practices to improve the delivery of mammography services. The proposed updates include requirements on recordkeeping, reporting, and communication of results. This proposed rule also addresses procedural requirements in several areas related to quality control and management of mammography facilities.

The benefits and costs associated with this proposed rule are summarized in Table 1. The quantified benefits are derived from reduced mortality and breast cancer treatment costs resulting from the breast density reporting requirements. We use two methods of measuring the value of reduced mortality: the value per statistical life (VSL) approach and an approach based on the value of lost quality-adjusted life years (QALY). Under the VSL approach, the estimate of annualized benefits over 10 years ranges from $73.24 million to $466.75 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from $85.33 million to $ 534.03 million. Under the QALY approach, the estimate of annualized benefits over 10 years ranges from $16.27 million to $77.23 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from $16.27 million to $ 61.77. Because there is uncertainty in the literature about the most appropriate method for analyzing reduced mortality for the population affected by this proposed rule, we do not present a primary value and use estimates from both methods to create the range of values in Table 1. The high estimate in Table 1 is based on the VSL approach, which yields the higher bound estimate of the two methods.

The low estimate is based on the QALY approach, which yields the lower bound estimate of the two methods. Other benefits that we are not able to quantify include improvements in the accuracy of mammography by improving quality control and strengthening the medical audit, and effects on morbidity.

The costs of the proposed rule include costs to mammography facilities to comply with the proposed requirements and costs associated with supplemental testing and biopsies resulting from the breast density requirements. The estimate of annualized costs over 10 years ranges from $34.96 million to $60.50 million at a 7 percent discount rate with a primary value of $47.03 million. Using a 3 percent discount rate, the annualized costs range from $33.86 million to $59.40 million with a primary value of $45.92 million. The primary estimate of the present value of costs over 10 years is $330.29 million at a 7 percent discount rate and $391.74 million at a 3 percent discount rate.

Table 1. Summary of Benefits and Costs in millions 2017 Dollars Over a 10 Year Time Horizon

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $/year		$16.27	$466.75	2017	7%	10 years	
			$16.27	$534.03	2017	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Improvements in the accuracy of mammography and better management of mammography facilities.						
Costs	Annualized Monetized $/year	$47.03	$34.96	$60.50	2017	7%	10 years	
		$45.92	$33.86	$59.40	2017	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers						7%		

	Federal Annualized Monetized $/year					3%		
	From/ To	From:			To:			
	Other Annualized Monetized $/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government:							
	Small Business: Annual cost per affected small entity estimated as $357-$623, which would represent a maximum of 2.7 percent of annual receipts							
	Wages:							
	Growth:							

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these costs this proposed rule would be considered a regulatory action under EO 13771.

Table 2. EO 13771 Summary Tables in Millions 2016 Dollars Over an Infinite Time Horizon

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$615.44	$446.14	$804.56	$1,378.67	$983.65	$1,819.96
Present Value of Cost Savings	$0	$0	$0	$0	$0	$0
Present Value of Net Costs	$615.44	$446.14	$804.56	$1,378.67	$983.65	$1,819.96
Annualized Costs	$43.08	$31.23	$56.32	$41.36	$29.51	$54.60
Annualized Cost Savings	$0	$0	$0	$0	$0	$0
Annualized Net Costs	$43.08	$31.23	$56.32	$41.36	$29.51	$54.60

II. Preliminary Regulatory Impact Analysis

A. Background

Mammography is an X-ray imaging examination used to identify signs of breast cancer. For women to receive the full benefit of mammography, the service must be of high quality, including performance of the examination by qualified technologists; using equipment which is tested and properly functioning; interpretation by qualified physicians; and clear and prompt communication of results to patients and their referring health care providers. The FDA is proposing to update the mammography regulations that were issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). The MQSA establishes uniform baseline Federal standards designed to ensure that all women nationwide have access to quality mammography services, and its implementing regulations address standards for accreditation bodies and certifying agencies, qualifications of personnel at mammography facilities, standards for mammography equipment, quality assurance testing, recordkeeping, and communication of results. This proposed rule would update the regulations by incorporating current science and mammography best practices.

FDA is proposing a number of changes to the mammography report in the MQSA regulations that are intended to facilitate communication between mammography facilities, healthcare providers and patients; facilitate the retrieval of mammography images; and help ensure that health care providers and patients are obtaining the necessary information from the mammography facility to enable a woman and her health care provider to make informed medical decisions, including breast density notification requirements.

Current regulations do not require that a notification of breast density be part of the report provided to the health care provider or the lay summary be provided to the patient. However,

there is increasing interest in breast density reporting. Thirty-four states have passed laws mandating notification of breast density, although the laws impose requirements that vary from state to state. To ensure all women receive consistent breast density information from their mammograms, FDA is proposing to amend the mammography reporting requirements to require that the written report of the results of the mammographic examination be provided to the health care provider and the lay summary of the results be provided to the patient also include information concerning patient breast density.

B. Market Failure Requiring Federal Regulatory Action

Information asymmetry implies that information may not be equal on both sides of a market. The market failure that this proposed rule seeks to address is the information asymmetry that exists when patients may not be fully informed of breast density information. The MQSA and current regulations require a mammography facility to provide a written report on each mammographic examination to the patient's health care provider. The mammography facility is also required to provide a summary of the report in lay language to the patient. However, current regulations do not require that a notification of breast density be part of the report provided to the health care provider or the lay summary provided to the patient.

Breast density refers to the proportion of fibroglandular tissue in the breast, as seen on a mammogram. Mammograms of breasts with higher density are harder to interpret than those of less dense breasts, because the dense tissue can obscure cancers (American College of Radiology, 2017). Dense breast tissue is one of the factors that increases the chances that a woman will develop breast cancer, and accordingly is listed as a risk factor for breast cancer. (Boyd, et. al., 2007; Centers for Disease Control and Prevention, 2017). As a result, some women with dense breasts may choose to undergo additional screening. Additional screening of

women with dense breasts can detect some additional cancers and reduce delays in treatment (Kolb, et al., 2002; Leconte, et al., 2003; Berg, et al., 2008).

There is increasing public awareness of the benefits of breast density reporting. Between 2009 and May 2018, 34 states[1] have passed laws mandating notification of breast density. The legislative action taken at the state level further provides evidence of a market failure at the federal level, since states have begun to act on their own in place of federal changes under the MQSA. This has also led to an increase in the salience of density reporting.

Although several states have passed laws requiring density reporting, federal regulation is still necessary. There remain 16 states without any density notification requirements. Furthermore, state laws impose requirements that vary from state to state, such that all women in covered states do not receive the same type of information. State reporting requirements range from information about breast density in general to specific information on a patient's breast density level and risk factors. This proposed rule would enact a standard requirement that would ensure that all patients and providers receive complete and consistent breast density information in mammography reports.

Market failure arising from inadequate information can provide an economic rationale for the government to intervene to ensure that breast density information is provided to all patients. The variation in state notification requirements makes it unlikely that consistent and detailed density notification requirements for all patients would arise through market forces. Proposing nationwide requirements that patients and their providers receive comprehensive information about breast density after a mammogram addresses the market failure of inadequate information about breast density and its implications.

[1] After this RIA was completed, one additional state has passed a breast density notification law to yield a total of 35 states.

If a woman has dense breasts and neither the report nor lay summary contains the notification, the woman and her provider would not know her density status and additional screening that would potentially be undertaken under full information may not be undertaken. If the mammography report contains the notification but the lay summary does not, a woman may remain uninformed, either due to provider oversight or due to the provider not recommending additional screening for the case in question. Even for cases in which additional screening would not be recommended by a health care provider, breast density notification would provide material information regarding the limitations of a negative mammographic finding for women with dense breasts.

Given that patients and providers may not have access to information about a mammographic feature that increases the risk for developing breast cancer, this proposed rule would provide information to better inform choices of whether to obtain follow up tests. We do not have information on the proportion of women who already receive comprehensive information about breast density from their physician, but for women who do not, the notification proposed to be included in the lay summary would enable them to better understand the meaning of their mammographic result. Irrespective of the information women currently receive from their physician, this notification in the proposed rule would provide them with a cue that may cause increased numbers to follow through with any additional screening.

C. Purpose of the Proposed Rule

MQSA was enacted to ensure that all women have access to quality mammography for the detection of breast cancer in its early, most treatable stages. Its provisions encompass facility accreditation, facility certification, and mammography quality standards. FDA's regulations implementing MQSA have been amended since their inception, and the currently proposed

amendments are designed to, among other things, address subsequent changes in mammography technology as well recommendations made in the Institute of Medicine's (IOM) 2005 report (IOM, 2005).

Based on technology changes in mammography and our experience with the administration of the MQSA program, FDA is proposing updates to the mammography regulations that are intended to better address the protection of public health. These updates would modernize the regulations by addressing mammography technologies that were not in use at the time the current regulations were published; help to ensure the availability of appropriate records for comparison purposes to enhance the benefit of mammography; require facilities to provide more information, including breast density information, to patients and their health care providers to allow for more informed health care decision making; further standardize the communication of mammography results to patients and providers to more clearly address the need for additional workup or follow up.

D. Baseline Conditions

The baseline for this analysis is determined by the current standard practice of mammography facilities and state level density regulations as it relates to the provisions in the proposed rule. We consulted FDA's Division of Mammography Quality Standards and ERG in determining the degree to which current standard practices align with provisions of the proposed rule. New proposed requirements relating to statistics reporting are included in the proposed rule, as well as provisions that would require that facilities make plans for retention and transfer of personnel records, mammograms, and patient reports in the event of facility closure. Additional assessment categories in mammography reports would also allow for more precise

categorization of mammography results and reflect the current practice of mammography. These changes would have incremental effects on mammography facilities as well as to patients.

Additionally, current MQSA regulations do not require breast density reporting in the mammography report or lay summary. Although the mammography report often includes this information, the frequency of inclusion is unknown. As of May 2018, 34 states have passed legislation requiring information about breast density to be communicated to patients[2]. We assume that in the baseline the states currently without density reporting requirements would remain the same in the absence of this proposed rule[3].

E. Benefits of the Proposed Rule

We consider the potential impact of the proposed rule on the accuracy of mammography as well as the impact of potential behavioral changes induced by the breast density notification requirements[4].

1. Accuracy of Mammography

The proposed rule will modify procedural requirements in several areas[5]. Such improvements in procedures might result in better quality control and management of mammography facilities. There are, however, no data with which to develop a quantitative estimate of the impact of such changes on public health.

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[2] http://densebreast-info.org/legislation.aspx.

[3] We note that there is a tendency toward underestimation due to an assumption that all states covered by density notification laws communicate density levels to patients. In section B we note that there is variation among states in the level of density information reported to patients. If more states add density reporting requirements or if density reporting were to become widespread on a voluntary basis, then we would overstate the impact of this proposed rule. It is also possible that women living in states without reporting requirements see radiologists in states with the requirement, and vice-versa, which also adds to the uncertainty of baseline density reporting. Breast density reporting may also be influenced by the recommendations of professional medical organizations.

[4] Our discussion of benefits is partially adapted from Section 5 of ERG's Final Report (2012a) and ERG's breast density addendum (2012b).

[5] We do not anticipate that this would lead to facility closures or reduction in services. We seek comment on this issue in addition to all aspects of the analysis.

This proposed rule could potentially improve the accuracy of mammography by improving quality control, strengthening the medical audit and ensuring that records are properly maintained for comparison purposes. FDA is proposing to clarify the minimum required components of the medical outcomes audit, including the calculation of three clinically significant metrics known as positive predictive value, cancer detection rate, and recall rate. Mammography accuracy can be evaluated by sensitivity, specificity, positive predictive value, and negative predictive value which are in turn defined by true positives, false positives, true negatives, and false negatives (ERG, 2012a). Calculating and tracking these three audit metrics would allow facilities and interpreting physicians to review their performance, evaluate their accuracy in detecting breast cancer, and enact quality improvement measures as necessary. Proper records management is also important in maintaining quality in mammography services. This proposed rule would ensure that patient and personnel records made available to patients and personnel after the facility's closure. The ability to compare previous mammography examinations is often necessary to make an accurate final assessment. Delays in the transfer of patient records can also lead to delays in diagnosis or treatment. Additionally, when personnel cannot obtain copies of their MQSA records to document their MQSA qualifications, they may not be able to work at additional or new facilities, which can lead to reduced public access to mammography services.

Improvements in the accuracy of mammography results could lead to a reduction in the number of false positives and false negatives. Table 3 shows the general relationship between true and false positives, true and false negatives, sensitivity, and specificity. Results from estimating annual values for screening mammography in the U.S. are shown in Table 4 and

described in the following paragraph. Because data on sensitivity are difficult to obtain and estimates vary, calculations are presented using both a high and low estimate of sensitivity.

Noone, et. al (2018) estimates that there will be 266,120 new female breast cancer cases diagnosed in 2018. Assuming that these diagnoses are accurate, this suggests 266,120 true positives each year. Approximately 11 percent of screening mammograms produce false-positive results (Brewer, et al., 2007). As of May 1, 2018, there were 39,328,699 total annual mammography procedures reported to FDA by MQSA accrediting bodies, based on facility-provided information (FDA, 2018). Agency data collected from the accreditation bodies, provided to them by facilities, indicate that approximately 76 percent[6] of the total procedures reported were screening mammograms, yielding a total of 29,889,811 exams. This suggests that there are approximately 3,287,879 (0.11 x 29,889,811) false positives a year in the initial screening.

The number of false negatives can be deduced from the sensitivity estimates as specified in Table 3. Using a higher sensitivity estimate of 79 percent as provided in Rosenberg et al.,(2006) would mean that the number of true positive screening mammograms divided by the total number of cases of cancer (total number of condition positives) each year is equal to 79 percent. Thus, the total number of condition positives is 366,861 (266,120 / 0.79). Subtracting the number of true positives (266,120) from the total condition positive cases (336,861) indicates that there are 70,741 false negative screening mammograms a year. Using the lowest estimate of sensitivity of 66 percent (Pisano et al., 2005) and performing the same calculations indicates that there are 403,212 condition positives (266,120 / 0.66) and 137,092 false negative screening mammograms (403,212 – 266,120). Finally, subtracting the sum of true positive (266,120), false

[6] This percentage is only an estimate due to the possibility of over or under reporting by facilities.

positive (3,287,879), and false negative (70,741 to 137,092) screening mammograms from the total number of screening mammograms (29,889,811) suggests between 26,198,720 and 26,265,071 true negative screening mammograms per year.

Table 3. Sensitivity and Specificity Definitions

		True Condition	
		Positive	**Negative**
Test Outcome	**Positive**	True Positive	False Positive
	Negative	False Negative	True Negative
	Sum	Total Positive Cases	Total Negative Cases
	Sensitivity	Sensitivity = $\frac{\sum True\ Positive}{\sum Condition\ Positive}$	
	Specificity		Specificity = $\frac{\sum True\ Negative}{\sum Condition\ Negative}$

Source: ERG (2012a)

Table 4. Screening Mammography Sensitivity and Specificity

79 Percent Sensitivity Estimate				
		True Condition		
		Positive	**Negative**	**Sum**
Test Outcome	Positive	266,120	3,287,879	3,553,999
	Negative	70,741	26,265,071	26,335,812
	Sum	336,861	29,552,950	29,889,811
	Sensitivity	79.0%		
	Specificity		88.9%	
66 Percent Sensitivity Estimate				
		True Condition		
		Positive	**Negative**	**Sum**
Test Outcome	Positive	266,120	3,287,879	3,553,999
	Negative	137,092	26,198,720	26,335,812
	Sum	403,212	29,486,599	29,889,811
	Sensitivity	66.0%		
	Specificity		88.9%	

Table 4 shows that screening mammography yields over 3 million false positives each year. False positives often lead to additional screening or biopsies. The cost of a breast ultrasound with image documentation is estimated to be $106.11 and the total cost of a needle

core breast biopsy and pathology is estimated to be $196.44 (ERG, 2012b[7]). Reducing false positives has the potential to reduce the costs associated with unnecessary interventions as well as short-term anxiety on the part of affected women.[8]

Reducing false negatives would improve public health by helping to ensure that cancer is detected and treated as early as possible. In the context of screening mammography, a false negative result means that routine mammography fails to detect cancer in an asymptomatic woman when it is present, thus delaying treatment. Reducing false negatives would also mean increasing mammography's sensitivity (i.e., increasing the proportion of screened women with breast cancer who have abnormal mammographic results).

Women with false negative screening mammograms would typically face delays in diagnosis and treatment until they either experience symptoms of breast cancer or have another mammogram a year or more later. Because five year survival rates decrease with more advanced stages at diagnosis and with tumor size (American Cancer Society, 2008) and cancer undetected by screening mammography might progress in stage or increase in size before it is detected, a delay in detection due to false negative screening mammograms could lead to increased morbidity and mortality.

Table 4 shows that screening mammography produces an estimated 70,000 to 137,000 false negatives each year. Martin et al. (1979) and Yankaskas et al. (2001) estimate that 29 percent of cancers in false negative mammograms are detectable. This means that between 20,515 (29 percent of 70,741) and 39,757 (29 percent of 137,092) cancers that could be detected on screening mammograms annually are not. We are unable to estimate to what extent this proposed rule would affect the number of false negatives, but given the large health

[7] Estimates were updated to 2017 dollars.
[8] For further discussion of the short-term anxiety caused by false positive mammograms, see Totson, et al. (2014).

consequences of early cancer detection, any reduction could yield substantial public health benefits. We also note, however, that cancers undetected by screening mammography might be inherently different from cancers that are detected. Therefore, using data for women with true positive screening mammograms may not lead to an accurate estimate of the potential reduction in morbidity and mortality for women with false negative screening mammograms.

Eliminating false negatives is a challenge with any screening test. The fact that many are due to characteristics of the woman or tumor means that the scope for regulation to reduce morbidity and mortality is limited. False negatives due to human error may be difficult to eliminate. Insofar as the MQSA regulations improve quality through provisions set forth in this proposed rule, they could reduce at least some portion of these preventable false negatives and thus reduce morbidity and mortality.

Other individual provisions also serve to amplify beneficial elements of the proposed mammography regulation, although the impact of these changes could not be quantified. Specifically, the proposed regulation requires facilities to retain mammograms for up to ten years and transfer them upon patient request; under the proposed rule, such requirements would apply even if a facility closes. Cady & Michaelson (2001) suggest that the availability of an earlier mammogram for comparative review can reduce false positives by half. Thus, while we lack any means to predict how often past mammograms would be lost upon facility closure without this provision, it appears likely that some patients would benefit from the record retention that otherwise might not occur. Facility closures in the past have sometimes led to problems in preserving the exam records. Thus it is possible that in some instances, due to these proposed provisions, interpreting physicians would be better able to interpret exams.

2. Breast Density Notification Requirements

The proposed regulation includes provisions that would require the inclusion of breast density information in the mammography report and lay summary, and additional text about the effects of breast density on mammography's sensitivity in the lay summary. These provisions may result in supplemental ultrasound screening, or other supplemental screening, for some women with dense breasts. We discuss the size of the affected population and estimate the benefits of additional ultrasound screening that may be induced by the proposed regulation, if finalized. The benefits that are expected to result from this provision would be potential reductions in cancer treatment costs due to early cancer detection as well as reductions in breast cancer mortality and morbidity.

a. Affected Population and Health Gains

As discussed above, there are 29,889,811 screening mammograms performed each year. Approximately 87 percent, or 26,004,136, of screening mammograms show normal results (ERG, 2012b). Assuming 41 to 47 percent of screening mammograms show dense breasts (Poplack et al., 2005; Tice et al., 2008; Sprague et al., 2014; Kerlikowske et al., 2015), we estimate that between 10,661,696 and 12,221,944 normal mammograms show dense breasts each year. As of May 2018, 34 states have passed legislation requiring information about breast density to be communicated to patients. Based on U.S. Census population projections, these states cover approximately 84 percent of the U.S. population, while 16 percent of women reside in states that do not require breast density information to be communicated to patients. Assuming that mammograms are distributed among states proportionally according to population, approximately 1,701,412 (10,661,696 x 0.16) to 1,950,399 (12,221,944 x 0.16) normal mammograms would show dense breasts annually in states not already requiring density information to be communicated to patients. This represents the population affected by the

proposed density notification requirements. The proposed density reporting may lead to additional testing.[9] Some additional action would be recommended for women with abnormal results regardless of the breast density results. Our analysis does not include additional testing that is recommended based on factors other than breast density information. If some lay summaries now include density information where they are not required by law, the number of new lay summary notifications would be lower than we assume here.

We do not have information on the proportion of women who already receive comprehensive information about breast density from their physician, but for women who do not, the notification proposed to be included in the lay summary would enable them to better understand the meaning of their mammographic result. Regardless of what information women receive from their physician, this notification would provide them with an indication that may cause increased numbers to follow through with any additional screening. [10] However, not every patient with dense breasts would be advised to undergo ultrasound screening, and not every patient advised to do so would do so. Connecticut was the first state to pass a breast density notification law. After its implementation, several studies were conducted on the utilization of ultrasounds for women with dense breasts. The literature suggests that, of the normal, dense, mammograms uncovered by state density reporting laws, approximately 40 percent would be recommended by their health care provider to undergo additional screening. This research also indicates that between 16.4 percent and 30 percent of those patients in Connecticut who were advised to undergo supplemental screening ultrasound did undergo that exam (Weigert and

[9] We note that the proposed provision could also result in an increase in additional testing in states with existing density notification legislation, which may understate our estimates of the affected population.
[10] We seek comment on whether there is the potential that mammography facilities will be overwhelmed by an increase in demand for additional screening.

Steenbergen 2012; Holley et al., 2012).[11] By multiplying the number of women with dense breasts in states without breast density laws by the percentage of women who undergo additional ultrasound screening, we estimate that between 111,613 (1,701,412 x 0.40 x 0.164) and 234,048 (1,950,399 x 0.40 x 0.30) women would undergo supplemental ultrasound screening annually.

Adjunct ultrasound screening in high-risk women with dense breasts results on average in the detection of 4.2 additional cancers per 1,000 women (Berg et al., 2008; Scheel et al. 2015). Applying this rate to the number of women undergoing supplemental ultrasound screening results in 469 ((111,613/1,000) x 4.2) to 983 ((234,048/1,000) x 4.2) additional cancers detected annually as a result of the breast density notification provision, with a primary value of 712 ((169,444/1,000) x 4.2).

Some of the public health benefit from this proposed rule would come from a reduction in breast cancer related fatalities. Because survival rates are higher for cancers detected at an earlier stage, early cancer detection due to supplemental ultrasound for women with dense breasts may result in a reduction in cancer fatalities. To estimate the annual number of breast cancer related fatalities that could be averted, we use estimates reported in an analysis by Sprague et.al (2015). In this analysis, the authors assess the effects of supplemental screening ultrasonography for women with dense breasts using three established Cancer Intervention and Surveillance Modeling Network breast cancer models. The models incorporate evidence from clinical trials and observational studies to estimate the effect of various screening scenarios on several breast cancer outcomes, including breast cancer mortality. It is estimated that, compared with biennial mammography screening alone, supplemental ultrasonography screening for women with dense breasts would avert 0.36 additional breast cancer deaths per 1,000 women.

[11] A follow up study shows that the percent of patients may be slightly higher, so our estimate is a lower bound.

Multiplying this fatality estimate by the number of women undergoing additional ultrasound screening per year yields 40 (0.36 x (111,613/1,000)) to 84 (0.36 x (234,048/1,000)) deaths per year that could be averted as a result of the breast density notification provision, with a primary estimate of approximately 61 (0.36 x (169,444/1,000)) deaths averted.

We project that the full public health benefits will accumulate over a period of 10 years, but the timing of the benefits from early cancer detection and avoided deaths accrue over a lagged period. We assume that the early detection in breast cancer cases would begin 3 years after the effective date of the final rule if the proposed rule is finalized, and the reduction breast cancer deaths would begin 6 years after the effective date.[12] The full effects over a 10 year period correspond to a total of 3,281 to 6,881 early cancers detected with a primary estimate of 4,982. Total averted deaths at the full benefit level ranges from 161 to 337, with a primary estimate of 244. Tables 5 and 6 shows the stream of early cancers detected and averted deaths over a 10 year period.

Table 5. Total Early Cancers Detected Over a 10 Year Period

Year	Low	Primary	High
1	0	0	0
2	0	0	0
3	0	0	0
4	469	712	983
5	469	712	983
6	469	712	983
7	469	712	983
8	469	712	983
9	469	712	983
10	469	712	983
Total	**3,281**	**4,982**	**6,881**

[12] Our analysis assumes that supplemental testing will lead to early cancer diagnosis, such that in absence of the proposed rule if finalized, cancer would be detected at a later stage and time period. Additionally, the median age at death from breast cancer is 6 years past the median age at diagnosis. As such, we assume a 3 year latency period for realization of early cancer detection benefits and a 6 year lag for avoided cancer death. We incorporate these lags in each section of the benefits analysis below. We request comments on these assumptions.

Table 6. Total Deaths Averted Over a 10 Year Period

Year	Low	Primary	High
1	0	0	0
2	0	0	0
3	0	0	0
4	0	0	0
5	0	0	0
6	0	0	0
7	40	61	84
8	40	61	84
9	40	61	84
10	40	61	84
Total	**161**	**244**	**337**

b. Reduced Cancer Mortality

We value avoided breast cancer deaths using two different methods: the average value of a statistical life and the value of the quality-adjusted life years saved. The value per statistical life (VSL) approach uses a range of VSL estimates to measure the value of reduced cancer mortality. VSL estimates do not represent the dollar value of a person's life, but a statistic that represents the amount society would be willing to pay to reduce the probability of death. We use VSL estimates based on a review of published studies by Robinson and Hammitt (2016). The estimates of VSL are in 2017 dollars and range from $4.6 million to $15.0 million, with a mid-point value of $9.9 million. VSL values in future years are adjusted for projected real income growth. The Congressional Budget Office (CBO) projects real income growth at 1.6 percent per year through 2025, and 1.4 percent in each year after 2025 (Congressional Budget Office [CBO], 2015). These VSL estimates are multiplied by the corresponding estimated number of averted deaths for each year as described above. We apply 3 and 7 percent discount rates to estimate the present discounted value of the averted deaths in each year, and the values for each year are summed across the 10 year period to give the present discounted value.

The second method for estimating the value of avoided breast cancer deaths uses the value of lost quality-adjusted life years (QALY)[13]. We also present this approach for valuing mortality reductions because the age distribution of breast cancer patients is older than in the general population used to estimate VSL. The value of QALYs approach accounts for these age differences by estimating the expected future quality-adjusted life years for an age distribution specific to breast cancer patients. To generate these estimates, we use QALY values from Sprague et.al (2015) and assume that supplemental screening would yield 1.7 additional QALYs for each affected patient.

To monetize these estimated gains for premature deaths averted, we construct measures of the value per QALY. These are derived from the VSL estimates discussed above. The VSL estimates are divided by the present discounted quality-adjusted life years remaining for an individual 40 years in age (HHS 2016). The result is a value per QALY estimate for averted fatalities in each of the 10 years after a final rule takes effect if the proposed rule is finalized. The value per QALY in the first year ranges from $234,589 to $764,965 at a 3 percent discount rate and $389,985 to $1,271,364 at a 7 percent discount rate. Next, we multiply the estimates for quality-adjusted life years gained from an avoided death at the age of 62 by the value per QALY and the overall number of avoided deaths in each year after the final rule takes effect. Finally, we

[13] As noted in Circular A-4, the Memorandum to the President's Management Council on Benefit-Cost Methods and Lifesaving Rules and the 2015 Report to Congress on the Benefits and Costs of Federal Regulations, OMB recommends using both VSL and VSLY methods for valuing delayed mortality. VSL has the advantage of a more extensive empirical literature, whereas VSLY has the advantage of better alignment with the notion that lives are extended rather than permanently saved. For regulations intended to delay mortality, OMB guidance encourages discussion of these analytic tradeoffs without emphasizing either VSL or VSLY as a primary technique, except in cases where the empirical approach underlying one estimate is especially well tailored to the regulatory policy being analyzed or when a third benefit estimation method provides independent confirmation for one of the first two.

adjust the results with 3 and 7 percent rates of discount and sum across each year of the 10 year period.

c. Reduced Cancer Morbidity

In addition to lower cancer mortality, the proposed rule would have effects on health-related quality of life. Some women with breast cancer would receive the same treatment, and thus experience the same stream of health effects, with the only rule-induced difference being an acceleration in the timing. For others, however, the proposed rule could lead, after the initial effects of accelerated treatment, to an overall reduction in time spent suffering from cancer and its effects. These effects include the health costs of breast cancer and any physical or mental impacts associated with having or surviving cancer. We decline to quantify and monetize these avoided costs due to limited information on health-related quality of life effects. We request comment on the best method to quantify the morbidity effects.

d. Reduced Cancer Treatment Costs

Cancer costs increase with the stage of cancer, such that diagnosis at an earlier stage would lead to reduced treatment costs. Ultrasound has been shown to find cancers at an early stage, generally at a comparable or earlier stage than cancers detected by mammography (Houssami et al., 2009). Most cancers detected by ultrasound tend to be small in size, node negative, and classified at stage 0 or 1 (Kaplan, 2001; Bae et al., 2011, Scheel et al., 2015). As a result, women with ultrasound-detected cancer are more likely to have cancers with characteristics that lead to a better prognosis, such as small size and lack of lymph node involvement, and earlier cancer diagnosis (ERG, 2012b). We define the cancer treatment cost

savings as the difference between the cost of treating cancer at a later stage and treating cancer an earlier stage[14].

The additional cancer cases attributed to the proposed breast density notification requirement may lead to treatment cost savings due to the detection of cancer at an earlier stage. We estimate treatment cost savings as the sum of direct medical costs and non-medical costs. Direct medical costs include hospitalizations, screenings, physician visits, and other health services. Non-medical costs to patients that include time spent traveling to and from treatments, in treatment, and waiting on treatment.

We use values from several research analyses on direct medical costs of breast cancer to derive average estimates of treatment costs by stage at diagnosis[15]. The average treatment cost is $40,533 at the local stage, $64,709 at the regional stage, and $79,973 at the distant stage. Because ultrasound is more likely to detect cancer at the localized stage, we estimate the cancer treatment cost savings by subtracting the cost of treating local cancer from the average treatment costs of regional and distant cancer. Because the later-stage cancer is assumed to be detected three years further into the future, we also discount the cost savings. This calculation yields average annual cost savings of $18,519 at 7 percent and $25,669 at 3 percent discount rate.

Non-medical costs are derived from Yabroff et al. (2007), which estimates the additional time spent by cancer patients on travel, waiting time, consultations, and receiving treatment associated with the initial and last-year-of-life phases. Patient time estimates associated with medical care for breast cancer are 66.2 hours per year in the initial phase and 185.9 hours per

[14] There may be situations in which patients receive additional screening and treatment for cases that do not result in cancer. We do not capture the costs associated with undergoing unnecessary treatment, such as additional medical or anxiety costs, but we request comment that might facilitate additional estimation.
[15] Average treatment costs were derived from Blumen et al. (2016), Schousboe et al. (2011), Subramanian et al. (2011), Trogdon et al. (2017), and Vyas et al. (2017), and updated to 2017 dollar values.

year in the terminal phase. Cancer patients are likely to spend some amount of time on treatment during the continuing phase, also. However, we would expect the time spend to be substantially less than during the initial and terminal phases. We estimate an average time cost for cancer during each year of the continuing phase of treatment to be half of the time cost during the initial phase, or 33.1 (= 66.2 hours / 2) hours.

We use the national mean wage of $24.34 as our average hourly value of time[16] (U.S. Bureau of Labor Statistics, 2017). The estimated annual time costs per patient for each phase of care is $1,611 ($24.34 per hour * 66.2 hours) during the initial phase, $860 ($24.34 per hour * 33.1 hours) during the continuing phase, and $4,525 ($24.34 per hour * 185.9 hours) during the terminal phase. We discount the estimates to account for the three year lag. This yields an average annual cost savings of $1,889 at a 7 percent discount rate and $2,118 at 3 percent.

3. Summary of Total Benefits

Table 7 presents the subtotals for the mortality and treatment cost savings. Table 8 shows the discounted monetized stream of total benefits using VSL mortality estimates. Panel A of Table 9 summarizes the combined mortality and treatment costs savings associated with the proposed rule. The mortality estimates in this panel are based on estimates calculated using the VSL. Over a 10 year period, present discounted value of total benefits ranges from $514.39 million to $3.28 billion at a 7 percent discount rate, and $727.90 million to $4.56 billion at a 3 percent discount rate. Our primary estimates are $1.59 billion at a 7 percent discount rate and $2.22 billion at a 3 percent discount rate. The annualized values of the primary estimates are $226.55 million at a 7 percent discount rate and $260.29 million at a 3 percent discount rate.

[16] As a proxy for post-tax wages, we use the mean wage without adjusting for benefits. We ask for comment on this assumption.

In Panel B of Table 9 we summarize combined mortality and treatment costs savings with mortality estimates calculated using the value of QALY gained per averted death. Over a 10 year period, present discounted value of total benefits ranges from $114.30million to $542.45 million at a 7 percent discount rate, and $138.77 million to $526.92 million at a 3 percent discount rate. Our primary estimates are $283.93 million at a 7 percent discount rate and $295.42 million at a 3 percent discount rate. The annualized values of the primary estimates are $40.43 million at a 7 percent discount rate and $34.63 million at a 3 percent discount rate.

Table 7: Mortality and Treatment Cost Savings Over a 10 Year Period

Scope	Description	Discount Rate	Low	Primary	High
Mortality (VSL Approach)	Present Discounted Value	7%	$467.45	$1,527.31	$3,196.39
		3%	$645.06	$2,107.60	$4,410.85
	Annualized Value	7%	$66.55	$217.45	$455.09
		3%	$75.62	$247.07	$517.09
Mortality (QALY Approach)	Present Discounted Value	7%	$67.35	$220.07	$460.56
		3%	$55.92	$182.72	$382.40
	Annualized Value	7%	$9.59	$31.33	$65.57
		3%	$6.56	$21.42	$44.83
Treatment Cost Savings	Present Discounted Value	7%	$46.94	$63.86	$81.89
		3%	$82.84	$112.70	$144.51
	Annualized Value	7%	$6.68	$9.09	$11.66
		3%	$9.71	$13.21	$16.94

Note: Values are shown in millions of dollars, using 2017 dollar values.

Table 8. Total Benefits Over a 10 Year Period Using VSL Mortality Approach

Year	WTP at 7%	WTP at 3%
1	$0	$0
2	$0	$0
3	$0	$0
4	$19.77	$19.77
5	$19.77	$19.77
6	$19.77	$19.77
7	$684.01	$684.01

8	$694.64	$694.64
9	$705.43	$705.43
10	$704.16	$704.16
Total	$2,847.53	$2,847.53

Note: Estimates are based on primary values.
Values are shown in millions of dollars, using 2017 dollar values.

Table 9. Present Discounted Value of Health Benefits Over a 10 Year Period

Panel A: Combined VSL Mortality and Treatment Cost Savings

	Discount Rate	Low	Primary	High
Present Discounted Value of Total Benefits	7%	$514.39	$1,591.17	$3,278.29
	3%	$727.90	$2,220.30	$4,555.36
Annualized Value of Total Benefits	7%	$73.24	$226.55	$466.75
	3%	$85.33	$260.29	$534.03

Panel B: Combined QALY Mortality and Treatment Cost Savings

	Discount Rate	Low	Primary	High
Present Discounted Value of Total Benefits	7%	$114.30	$283.93	$542.45
	3%	$138.77	$295.42	$526.92
Annualized Value of Total Benefits	7%	$16.27	$40.43	$77.23
	3%	$16.27	$34.63	$61.77

Note: Values are shown in millions of dollars, using 2017 dollar values.

F. Costs of the Proposed Rule

The estimated costs of this proposed rule include costs incurred by mammography facilities and the costs associated with supplemental testing and biopsies incurred by patients[17].

[17] Mammography services have undergone rapid change in recent years. We recognize that continuing changes in the industry introduce additional uncertainty into the estimated baseline and incremental costs of the proposed rule. We therefore request comment on the estimates as well as the underlying inputs and assumptions.

1. Mammography Facilities Costs

a. Affected Entities

As of May 1, 2018, FDA's data on registered facilities showed that there were 8,691 facilities certified to perform mammography, operating 18,852 mammography units (FDA, 2018). Mammography is performed in private practices, clinics, health maintenance organizations, and hospitals. For cost estimation, we have classified facilities as small (one unit), medium (two units), or large (three or more units). The distribution of affected entities by size is presented in Table 10.[18]

Table 10. Mammography Facilities by Size

Size	**Number of Mammography Units**	**Number of Establishments**
Large	3 or more	986
Medium	2 units	1,995
Small	1 unit	5,710
Total		**8,691**

b. Approach to Estimating Costs

The costs to industry of complying with this proposed rule if finalized were estimated by identifying the incremental activities that would be required for new provisions, categorizing the provision according to the type of entity, estimating how well current practices satisfy the requirements of each provision in the proposed regulation (ERG, 2012b). Representatives of each type of affected entity and FDA's Division of Mammography Quality were consulted in deriving current costs. We found that baseline practices in some cases came close to satisfying some of the proposed new regulatory requirements. There is also a high level of uniformity of

[18]. We assume the proportion of mammography facilities that are large, medium, and small is the same as estimated by ERG (2012a).

baseline practices among mammography facilities; under baseline practices, some facilities' practices would satisfy most proposed new provisions without any changes, while virtually no facilities' practices would satisfy some of the proposed new provisions. No incremental costs would be incurred for provisions that are currently satisfied by all facilities. Where applicable, the costs for each entity are estimated on a provision-by-provision basis. Finally, we aggregate these per-entity costs to capture total costs over a 10-year time horizon.

Some of the changes in this proposed rule would add to or clarify existing regulatory requirements but would not generate incremental costs. Additionally, many provisions would generate negligible incremental costs (or savings), such as minor revisions to administrative procedures. We are not anticipating that this proposed rule would lead to facility closures or reduction in services, but we invite comment on this issue.

c. Facility Costs

The proposed rule would affect four types of staff members at mammography facilities: interpreting physicians, radiologic technologists, medical physicists, and administrative staff. The costs of complying with the proposed amendments are determined using input from health industry consultants and the facilities affected. Some costs will vary with the size of the facility; for example, larger facilities may require more time to develop procedures than smaller ones[19].

The proposed rule contains five provisions with nonzero estimated costs or cost savings affecting mammography facilities. Modifying mammography report forms by adding additional categories for the final and incomplete assessment and adding breast density information would make the largest contribution to the estimated one-time costs of this proposed rule. We note that our cost estimate assumes that current forms are not in alignment with the proposed rule and that

[19] Labor costs from ERG (2012a) were updated to 2017 wages and adjusted for benefits and overhead.

modification would require not only a change in the form, but also a change in procedure with associated costs for training, discussion, and coordination among staff within mammography facilities. Due to uncertainty about baseline practices regarding different provisions of the proposed rule, and the cost of implementing changes in mammography report forms, we request comment on our estimates of cost.

Several of the proposed provisions would lead to incremental annual costs for some mammography facilities.

Provisions for transfer of records in the event the facility closes – Facilities that close would incur costs to ensure that patient and personnel records are transferred to a nearby facility or otherwise made available to patients and personnel after the facility's closure. We assume that one percent of facilities would be closing on an annual basis and applied closing costs to those facilities. Because mammography facilities would generally attempt to transfer records appropriately to another facility, we estimated that 75 percent of closing facilities would undertake the transfer without the regulatory requirement. We assume that the notification requirement for facility closure would apply only to facilities that are closing within a foreseeable timeframe, and not to all other facilities operating normally.

Miscellaneous procedure rewriting and development – Where procedures for preparation of lay summaries need to be rewritten or supplemented, we allot time (approximately one-half the time required for initial development) to annually revisit the procedures to ensure their continued appropriateness and effectiveness. This time would be used to draft changes and then to circulate the procedures among the staff.

Provisions to include breast density reporting in lay summary– The proposed regulation includes provisions requiring that the written report of the results of the mammographic

examination provided to the health care provider and the lay summary of the results provided to the patient also include information concerning patient breast density. The costs associated with these provisions would result from making modifications to the mammography report and lay summary text.

Provisions for positive predictive value (PPV), cancer detection rate, and recall rate – Although the facilities contacted were all calculating the various statistics specified in this proposed provision, the literature on mammography quality measures suggests that not all mammography facilities are developing and compiling these statistics. Smaller facilities are somewhat less likely than larger facilities to be compiling these statistics. We allotted on average 40 hours per year for facilities to develop these statistics if they are not doing so currently.

Table 11 presents the per-facility costs for mammography facilities. This table takes into account current standard practice as well as facility size. We judged that small facilities would incur three-fourths of the costs of average facilities, and large facilities would incur 125 percent of the costs of average facilities. These scale factors were applied to all individual cost estimates.

Table 11. Mammography Facility Costs (per entity)

General		One-Time			Annual		
Provision	Action	Large	Medium	Small	Large	Medium	Small
900.12(a)(4)	Make personnel records available upon request and upon facility closing	$0	$0	$0	$9	$7	$5

900.12(c)(1)(iv-vi)[1]	Rewrite mammography report forms or insert new fields in electronic forms to allow for new assessment categories; add overall assessment of breast density	$5,699	$4,550	$3,412	$0	$0	$0
900.12(c)(2)(iii-iv)[2]	Include breast density reporting in lay summary	$1,048	$838	$629	$0	$0	$0
900.12(c)(4)(v)	Provide access to mammographic records if facilities are closed	$0	$0	$0	$9	$7	$5
900.12(f)(1)	Record PPV, Cancer Detection Rate, Recall Rate	$156	$251	$287	$370	$592	$665
Total		$6,903	$5,639	$4,328	$387	$605	$675

Source: ERG estimates adjusted to 2017 wage levels

Individuals from affected entities will need to devote time to reading and understanding this proposed rule if finalized. We assume an average of one health services manager at each facility will read the rule. At an adult average reading speed of 200-250 words per minute, we estimate that each reader will spend about 1 hour. We value the opportunity cost of one hour using the mean hourly wage of a medical and health services manager, which is doubled to account for benefits and overhead. We estimate the time spent learning about the rule at a cost of

$116.90 per facility (BLS 2017). Multiplying this estimate by the total number of mammography facilities yields a total one-time cost for reading the rule of $1,015,978.

2. Costs Associated with Supplemental Testing and Biopsies

The costs in this analysis also include costs associated with supplemental testing and biopsies resulting from the proposed breast density notification requirement. This provision would require, among other things, that women with dense breasts be informed of their breast density in the lay summary report of the screening mammography, which may lead to supplemental ultrasound or other supplemental screening for some women with dense breasts. Although supplemental screening may lead to additional cancer detection for women with dense breasts, it may also lead to an increase in the number of biopsies for women without cancer.[20] The costs related to this provision include the cost of supplemental ultrasound screening for women with dense breasts and the cost of unnecessary biopsies[21].

The cost of testing includes not only the cost of ultrasound but also the cost of any follow-up biopsies. As reported above, the cost of a breast ultrasound with image documentation is estimated to be $106.11 and the total cost of a needle core breast biopsy and pathology is estimated to be $196.44. As discussed above, we determine the number of women to receive ultrasound screening by multiplying the number of women with dense breasts living in states uncovered by density reporting requirements by the percentage of patients estimated to undergo screening. Using the range of 111,613 to 234,048 women with dense breasts receiving ultrasounds, we estimate the total annual cost of ultrasound screening of women with dense

[20] Supplemental screening may also result in an increase in the number of false-positives (Melnikow 2016). However, we do not have sufficient data to estimate the quantitative impacts.
[21] See Berg (2015) for additional discussion on additional costs that may arise as a result of supplemental screening, including the cost for screening MRI.

breasts is estimated to range from $11,843,340 to $24,835,082. Sprague et.al (2015) estimate that supplemental ultrasonography screening for women with heterogeneously or extremely dense breasts resulted in 354 biopsy recommendations per 1,000 women after a false-positive ultrasonography result. Multiplying this estimate by the number of women to undergo additional screening annually yields a total of 39,511 (354 x (111,613/1,000)) to 82,853 (354 x (234,048/1,000)) biopsies received. Multiplying this range by the average price of a biopsy yields the total cost of a biopsy ranging from $7,761,624 to $16,275,862. Adding the total cost of biopsies to the total costs of ultrasounds yields an annual cost ranging from $19,604,964 to $41,110,994, with a primary estimate of $29,763,158.

We also estimate patients' time costs associated with additional biopsies and ultrasounds. We assume that an average time required for a needle core breast biopsy and ultrasound is approximately one hour for each procedure[22]. We use the national mean wage of $24.34 as our average hourly value of time. Multiplying the value of time by the number of ultrasounds and biopsies yields the total time costs associated with each procedure. The time cost associate with additional ultrasounds is estimated to range from $2,716,651 (111,613 x $24.34) to $5,696,725 (234,048 x $24.34). The time cost associate with additional biopsies is estimated to range from $961,694 (39,511 x $24.34) to $2,016,641 (82,853 x $24.34). The total annual time costs to patients range from $3,678,346 to $7,713,366, with a primary estimate of $5,584,258.

3. Summary of Total Costs

Table 12 shows the stream of total undiscounted costs and Table 13 shows the stream of costs over a 10 year period. Present value and annualized costs are presented in Table 14.

[22] Sources: https://www.insideradiology.com.au/breast-core-biopsy/
https://www.insideradiology.com.au/breast-ultrasound/

Present value costs over a 10 year period range from $245.55 million to $424.94 million at a 7 percent discount rate, and $288.83 million and $506.70 million at a 3 percent discount rate. Our primary estimates are $330.29 million at a 7 percent discount rate and 391.74 million at a 3 percent discount rate. The annualized cost values of the primary estimates are $47.03 million at a 7 percent discount rate and $45.92 million at a 3 percent discount rate.

Table 12. Total Costs

Type	**One-time**	**Annual**		
		Low	**Primary**	**High**
Industry Cost-Mammography Facilities	$43.79	$5.44	$5.44	$5.44
Public Cost-Density Notification	$0.00	$23.28	$35.35	$48.82
Total	**$43.79**	**$28.73**	**$40.79**	**$54.27**

Note: Values are shown in millions of dollars, using 2017 dollar values

Table 13. Total Costs Over a 10 Year Period

Year	**Total Costs**		
	Low	**Primary**	**High**
1	$72.51	$84.58	$98.05
2	$28.73	$40.79	$54.27
3	$28.73	$40.79	$54.27
4	$28.73	$40.79	$54.27
5	$28.73	$40.79	$54.27
6	$28.73	$40.79	$54.27
7	$28.73	$40.79	$54.27
8	$28.73	$40.79	$54.27
9	$28.73	$40.79	$54.27
10	$28.73	$40.79	$54.27
Total	**$331.05**	**$451.70**	**$586.46**

Note: Values are shown in millions of dollars, using 2017 dollar values

Table 14: Present Value and Annualized Costs

	Discount Rate	Low	Primary	High
Present Discounted Value of Total Costs	7%	$245.55	$330.29	$424.94
	3%	$288.83	$391.74	$506.70
Annualized Value of Total Costs	7%	$34.96	$47.03	$60.50
	3%	$33.86	$45.92	$59.40

Note: Values are shown in millions of dollars, using 2017 dollar values

G. Distributional Effects

In this section, we summarize the potential impacts of the proposed rule on the federal budget as it relates to Medicare and Medicaid spending[23]. Because the rule may result in earlier detection of breast cancer, it can influence diagnosis and treatment services under Medicare and Medicaid, and ultimately increase the number of program beneficiaries who survive and subsequently incur routine lifetime medical expenses. To estimate these potential budget impacts, we analyze three different sets of outcomes: medical spending for additional ultrasound and biopsy procedures, reductions in cancer treatment costs for program beneficiaries, and the value of remaining lifetime and end-of-life medical expenses for averted deaths associated with the proposed rule. As discussed in detail in the Technical Appendix, the overall budgetary impact is negative; the estimated reductions in cancer treatment costs are more than offset by increases in diagnosis testing and expected lifetime spending by survivors.

Over the 10-year period following the effective date of a final rule if this proposed rule is finalized, the net present discounted value of additional public spending ranges from $34.33 to $197.07 million at a 3 percent discount rate, and $21.59 to $154.29 million at a 7 percent discount rate. Our primary estimates of the present discounted value of additional public spending are approximately $108.23 million at a 3 percent discount rate and $81.12 million at a 7 percent discount rate. The annualized values of the primary estimates are approximately $12.69 million at a 3 percent discount rate and $11.55 million at a 7 percent discount rate.

Table 15 - Present Discounted Value of the Net Impact on Medicare and Medicaid Spending, 10 Years After Rule Effective Date (millions of 2017 dollars)

	Discount Rate	Low	Primary	High

[23] We do not consider other types of federal budget implications, such as Social Security and tax revenues.

Panel A - Present Discounted Value of Additional Ultrasounds and Biopsies				
Present Discounted Value of Ultrasounds and Biopsies	3%	$28.92	$142.24	$302.60
	7%	$23.81	$117.12	$249.16
Annualized Value of Ultrasounds and Biopsies	3%	$3.39	$16.67	$35.47
	7%	$3.39	$16.67	$35.47
Panel B - Present Discounted Value of Reductions in Cancer Treatment Costs (sign change to indicate negative spending impact)				
Present Discounted Value of Treatment Cost Reduction	3%	($14.23)	($63.97)	($146.80)
	7%	($10.98)	($49.36)	($113.27)
Annualized Value of Treatment Cost Reduction	3%	($1.67)	($7.50)	($17.21)
	7%	($1.56)	($7.03)	($16.13)
Panel C - Present Discounted Value of Remaining Medical Spending After Averted Death				
Present Discounted Value Spending After Averted Death	3%	$19.65	$29.96	$41.26
	7%	$8.76	$13.36	$18.40
Annualized Value of Spending After Averted Death	3%	$2.30	$3.51	$4.84
	7%	$1.25	$1.90	$2.62
Panel D - Net Additional Public Spending				
Present Discounted Value of Net Impact on Public Spending	3%	$34.33	$108.23	$197.07
	7%	$21.59	$81.12	$154.29
Annualized Value of Net Impact on Public Spending	3%	$4.02	$12.69	$23.10
	7%	$3.07	$11.55	$21.97

H. International Effects

This proposed rule is based on mammography services preformed domestically. We therefore do not expect effects on international trade.

I. Uncertainty and Sensitivity Analysis

1. Uncertainty

In quantifying the public health benefits from breast density reporting, we recognize that uncertainties exist. Sources of uncertainty include the proportion of women with dense breasts and the percent of women that undergo additional screening[24]. To account for these

[24] We request comment on these inputs as well as the extent of baseline density reporting.

uncertainties, we use a Monte Carlo simulation and assume a uniform distribution. Results are reported for the mean values and the 5th and 95th percentiles, where the percentiles correspond to the extreme values of 90-percent confidence intervals associated with the estimated benefits. Table 16 displays present value and annualized benefits resulting from running Monte Carlo simulations.

As discussed in more detail in the Sensitivity section below, there is uncertainty about levels of voluntary reporting and relevant state requirements that would be experienced in the absence of this proposed rule. However, this uncertainty is not captured quantitatively in the Monte Carlo analysis. Instead, all results in Table 16 reflect several assumptions about current practices in the absence of this proposed rule: 1) the current state-level adoption of breast density notification would remain the same now and into the future; 2) if a state currently has breast density notification requirements, they are equivalent to those set forth in the proposed rule; and 3) there is no voluntary provision by healthcare providers of breast density information now or into the future. These assumptions about the baseline affect the incremental costs and benefits of the rule. We request comment on how to incorporate this uncertainty into the Monte Carlo simulations.

Table 16. Present Discounted Value of Health Benefits Over a 10 Year Period using Monte Carlo Simulations

Panel A: Combined Treatment Cost Savings, VSL Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of Total Benefits	7%	$568.36	$1,590.48	$3,047.94
	3%	$802.36	$2,219.34	$4,237.49
Annualized Value of Total Benefits	7%	$80.92	$226.45	$433.96
	3%	$94.06	$260.17	$496.76

Panel B: Combined Treatment Cost Savings and QALY Mortality

	Discount Rate	Low	Primary	High
Present Discounted Value of Total Benefits	7%	$122.07	$283.83	$509.26
	3%	$145.22	$295.34	$499.36
Annualized Value of Total Benefits	7%	$17.38	$40.41	$72.51
	3%	$17.02	$34.62	$58.54

Note: Values are shown in millions of dollars, using 2017 dollar values

2. Sensitivity

The costs and benefits in this analysis are sensitive to the number of states we assume would not have breast density reporting requirements in the absence of the proposed rule. There has been increasing interest in breast density at the state level over time. Since 2009, 34 states have adopted density notification laws and this appears to be an upward trend. In absence of the rule, we expect that there may be gradual adoption by more states over time. If all states independently adopt breast density reporting laws by the time of publication of the final rule if this proposed rule is finalized, the quantified benefits and costs estimated in the analysis would be overstated. Although MQSA would provide federal regulation to ensure that uniform guidelines related to breast density notification are implemented across the county, relative to an alternative baseline, in which density reporting would have become standard practice even in the absence of the rulemaking, there would be lower quantified benefits and costs attributable to the proposed rule if finalized.

J. Analysis of Regulatory Alternatives to the Proposed Rule

In our analysis of alternatives, we compare the total cost of the proposed rule with two options that would be less stringent and one option that would be more stringent. We only

consider provisions that have estimated costs in our analysis of regulatory alternatives. The first two alternatives would eliminate provisions in the proposed rule resulting in lower total costs, and the second alternative would slightly increase costs. The first regulatory alternative excludes the provisions related to the breast density notification requirements. The second regulatory alternative only includes breast density reporting and excludes the other costly provisions. The third regulatory alternative includes additional requirements for facilities that are not included in this proposed rule relating to administrative procedures and personnel matters, such as establishing written cleaning procedures and documenting personnel information. [25] This alternative gives an example of the implications of including supplementary requirements that are not directly related to mammography practice.

Table 17 presents the undiscounted one-time and annual costs for each alternative and for the proposed rule. Table 18 shows the present value and annualized costs at 7 percent and 3 percent discount rates.

Table 17. Total Costs of Alternatives

Scope	One-time	Annual		
		Low	Primary	High
Alternative 1	$3.31	$5.44	$5.44	$5.44
Alternative 2	$41.49	$19.60	$29.76	$41.11
Alternative 3	$45.49	$25.27	$35.43	$46.78
Proposed Rule	$43.79	$25.05	$35.21	$46.55

Note: Values are shown in millions of dollars, using 2017 dollar values

Table 18. Present Value and Annualized Costs of Alternatives Over a 10 Year Period

Scope	Description	Discount Rate	Low	Primary	High
Alternative 1	Present Discounted Value	7%	$41.54	$41.54	$41.54
		3%	$49.75	$49.75	$49.75
	Annualized Value	7%	$5.92	$5.92	$5.92
		3%	$5.83	$5.83	$5.83

[25] These costs were also estimated by ERG.

Alternative 2	Present Discounted Value	7%	$179.19	$250.53	$330.24
		3%	$206.64	$293.29	$390.09
	Annualized Value	7%	$25.51	$35.67	$47.02
		3%	$24.22	$34.38	$45.73
Alternative 3	Present Discounted Value	7%	$223.00	$294.35	$374.05
		3%	$261.08	$347.73	$444.53
	Annualized Value	7%	$31.75	$41.91	$53.26
		3%	$30.61	$40.76	$52.11
Proposed Rule	Present Discounted Value	7%	$219.72	$291.06	$370.77
		3%	$257.46	$344.11	$440.91
	Annualized Value	7%	$31.28	$41.44	$52.79
		3%	$30.18	$40.34	$51.69

Note: Values are shown in millions of dollars, using 2017 dollar values

The first regulatory alternative, which excludes the proposed density reporting requirements, would reduce the undiscounted one-time cost by $40.48 million, and reduce the annual cost between $19.60 million to $41.11 million. This option would substantially reduce the costs associated with the proposed regulation. However, the total benefits resulting from the breast density notification provision, including reduced mortality and breast cancer treatment, would also be greatly reduced. Because the monetary benefits for this proposed rule are solely derived from the breast density requirement, excluding these provisions would eliminate benefits with present discount values ranging from $514.39 million to $4.56 billion over a 10 year period.

The second alternative only includes the provisions related to the breast density notification requirements. This option would reduce undiscounted one time costs by $2.30 million and reduce annual costs by $5.44 million. Although this alternative would slightly reduce total costs, the full benefits of the proposed regulation would not be fully realized if the other provisions were excluded from the proposed rule. This would include unquantified benefits related to the accuracy of mammography that include improvements in quality control and records management.

The third alternative includes additional requirements not in the proposed rule that are administrative in nature. This option increases the one time costs by $1.71 million, and increases the annual costs by $0.22 million. The requirements in this alternative would not directly influence mammography practices, and would not result in any additional benefits that could be quantified. As such, this alternative would increase the cost of implementing the proposed regulation without corresponding medical benefits.

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because most facilities that will be affected by this rule are defined as small businesses, we find that the proposed rule will have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act[26].

A. Description and Number of Affected Small Entities

The FDA's registration database provides useful profile information and distributes mammography providers across 12 different FDA facility classifications. Table 19 lists each classification and the number of facilities judged to be actively practicing mammography in 2011.

Table 19: Facility Descriptions & Counts

Type	Title	Facilities
1	Private Practice - Radiology	1,863
2	Private Practice - Internal Medicine	52
3	Private Practice - OB GYN	422

[26] This discussion is partly derived from ERG (2012a).

4	Private Practice - Surgery	19
5	Private Practice - Other	56
6	Hospital - Radiology Dept.	3,896
7	Hospital - Non Radiology Dept.	178
8	Multiple Specialty Practice	1,230
9	Health Agency	51
10	Breast Clinic	563
11	Mobile Unit	90
99	Other	202
Total		8,624

Note: Totals may not be exact due to rounding.

Mammography facilities could fall within multiple North American Industry Classification System (NAICS) codes. This analysis considers two NAICS codes that capture mammography facilities: 621512 (Diagnostic Imaging Centers) and 622 (Hospitals). We assume that all mammography providers are represented in either of these two NAICS codes. As such, we estimate that there were 4,550 non-hospital facilities (all non-hospital entries in the table), and 4,074 hospitals (the sum of lines 6 and 7 in the table) that performed mammography in 2011. Assuming that hospitals account for the same proportion of mammography facilities in 2017, we estimate that there are 4,585 non-hospital facilities and 4,106 hospitals that perform mammography.

Data from the 2012 Economic Census provide a breakdown of facilities in these NAICS codes, by revenue size (U.S. Census Bureau, 2012). However, not all facilities in these NAICS codes provide mammography services. Using the counts of diagnostic imaging centers and hospitals above and distributing them proportionally across the revenue distribution from the Economic Census yields an estimated breakdown of mammography facilities by revenue size, as shown in Tables 20 and 21.

Table 20. Distribution of Revenues for Diagnostic Imaging Centers

	Number of Establishments	Mammography Facilities
All Establishments	6,809	4,585
Establishments Operated for Entire Year	6,042	4,069
< $10,000 receipts	4	3
$10,000 - $24,999 receipts	41	28
$25,000 - $49,999 receipts	99	67
$50,000 - $99,999 receipts	288	194
$100,000 - $249,999 receipts	660	444
$250,000 - $499,999 receipts	775	522
$500,000 - $999,999 receipts	990	667
$1,000,000 - $2,499,999 receipts	1,418	955
$2,500,000 - $4,999,999 receipts	932	628
$5,000,000 - $9,999,999 receipts	533	359
$10,000,000+ receipts	302	203
Establishments Not Operated Entire Year	767	517

Sources: 2012 Economic Census and ERG estimates.

The Small Business Administration (SBA) size standard for small diagnostic imaging centers is annual receipts under $15.0 million (SBA, 2017). Of the 4,069 mammography facilities projected to operate for the entire year, all but some of the 203 in the largest size category would be small according to the 2017 size standard. Thus, a minimum of 3,865 of the mammography facilities in operation for the entire year, or 95 percent of the total, would be small. However, because receipts may have grown since 2012, this comparison may overstate the number of small businesses.

Table 21. Distribution of Revenues for Hospitals

	Number of Establishments	Mammography Facilities
All Establishments	6,475	4,106
Establishments Operated for Entire Year	6,394	4,054
< $10,000 receipts	0	0
$10,000 - $24,999 receipts	0	0
$25,000 - $49,999 receipts	0	0
$50,000 - $99,999 receipts	0	0
$100,000 - $249,999 receipts	0	0
$250,000 - $499,999 receipts	1	1
$500,000 - $999,999 receipts	1	1

$1,000,000 - $2,499,999 receipts	12	8
$2,500,000 - $4,999,999 receipts	127	81
$5,000,000 - $9,999,999 receipts	462	293
$10,000,000+ receipts	5,791	3,672
Establishments Not Operated Entire Year	81	51

Sources: 2012 Economic Census and ERG estimates.

The SBA size standard for small hospitals is annual receipts under $38.5 million (SBA, 2017). Of the 4,054 hospitals with mammography in operation for the entire year, all but some of those in the largest revenue category would be small according to the 2017 size standard. Therefore, a minimum of 382 (the sum of all hospitals with less than $10 million in annual receipts), or 9 percent of the total, are small. In addition, an unknown number of the 3,672 hospitals with receipts of $10 million or more would be small.

B. Description of the Potential Impacts of the Proposed Rule on Small Entities

We compiled the costs associated with the proposed rule and compared it to the estimated annual receipts of mammography facilities. Because our revenue information comes from 2012, for the purposes of the small entity analysis we re-estimate costs valuing labor at 2012 wages. Tables 22 and 23 present the calculations for diagnostic imaging centers and hospitals. The estimated one-time cost is $4,100 to $6,474 per facility, depending on its size classification. The estimated annual cost is $357 to $623 per facility.

Table 22: Small Business Costs as a Percentage of Receipts at Diagnostic Imaging Centers

Receipts Size	Number of Mammography Facilities	Average Receipts	One-time Cost	One-time Cost as a % of Receipts	Annual Cost	Annual Cost as a % of Receipts
<24,999	30	$15,356	$4,100	26.7%	$623	4.1%
$25,000 - $49,999	67	$38,616	$4,100	10.6%	$623	1.6%
$50,000 - $99,999	194	$74,934	$4,100	5.5%	$623	0.8%
$100,000 - $249,999	444	$169,203	$4,100	2.4%	$623	0.4%
$250,000 - $499,999	522	$367,015	$4,100	1.1%	$623	0.2%
$500,000 - $999,999	667	$732,628	$4,100	0.6%	$623	0.1%

$1,000,000 - $2,499,999	955	$1,639,807	$4,705	0.3%	$590	0.0%
$2,500,000 - $4,999,999	628	$3,536,797	$5,309	0.2%	$558	0.0%
$5,000,000 - $9,999,999	359	$6,877,614	$5,892	0.1%	$458	0.0%
$10,000,000+ receipts	203	$19,612,854	$6,474	0.0%	$357	0.0%
Establishments Not Operated Entire Year	517	$408,396	$4,100	1.0%	$623	0.2%

Source: 2012 Economic Census and ERG estimates.

Table 23: Small Business Costs as a Percentage of Receipts at Hospitals

Type of Establishment	Number of Mammography Facilities	Avg Receipts ($)	Up-front Cost ($)	Up-front Cost as a % of Receipts	Annual Cost ($)	Annual Cost as a % of Receipts
$100,000 - $249,999	0	NA				
$250,000 - $499,999	1	NA				
$500,000 - $999,999	1	NA				
$1,000,000 - $2,499,999	8	$2,050,750	$4,100	0.20%	$623	0.03%
$2,500,000 - $4,999,999	81	$3,978,000	$4,100	0.10%	$623	0.02%
$5,000,000 - $9,999,999	293	$7,649,387	$4,100	0.05%	$623	0.01%
$10,000,000+	3,672	$150,253,726	$5,295	0.00%	$513	0.00%
Establishments Not Operated Entire Year	51	$32,923,506				

Source: 2012 Economic Census and ERG estimates.

As shown in Table 22, one-time costs are 26.7 percent of receipts and annual costs are 4.1 percent of receipts for the smallest diagnostic imaging centers (those with annual receipts of less than $24,999). Based on this and the other estimates in the table, we conclude that the proposed rule, if finalized, would have a significant impact on a substantial number of small entities. The proposed regulation would have smaller effects on hospitals because they provide more diversified services and tend to be larger. As shown in table 23, in the smallest hospital size category for which we have receipts information, the one-time cost would be 0.20 percent of receipts and the annual cost would be 0.03 percent of receipts.

C. Alternatives to Minimize the Burden on Small Entities

Regulatory alternatives 1 and 2, described in Section J, would reduce costs for all mammography facilities. Therefore, these alternatives offer potential regulatory relief for small entities. Below we show how the reduction in cost under these alternatives would reduce the cost of this proposed rule on diagnostic imaging centers.

As shown in table 24, under the first regulatory alternative, the one time costs per mammography facility would be $251 to $373. This is a relatively large reduction of between $3,727 and $6,223 compared with the proposed rule. The annual costs per facility would be between $357 and $623, which is no change from the proposed rule. Firms in the small size class experience the smallest reduction in one-time costs compared with the proposed rule. For the smallest diagnostic imaging centers, one-time costs would be 2.4 percent of receipts and annual costs would be 4.1 percent of receipts.

Table 24: Small Business Costs as a Percentage of Receipts at Diagnostic Imaging Centers under Regulatory Alternative 1

Receipts Size	Number of Mammography Facilities	Average Receipts	One-time Cost	One-time Cost as a % of Receipts	Annual Cost	Annual Cost as a % of Receipts
<24,999	30	$15,356	$373	2.4%	$623	4.1%
$25,000 - $49,999	67	$38,616	$373	1.0%	$623	1.6%
$50,000 - $99,999	194	$74,934	$373	0.5%	$623	0.8%
$100,000 - $249,999	444	$169,203	$373	0.2%	$623	0.4%
$250,000 - $499,999	522	$367,015	$373	0.1%	$623	0.2%
$500,000 - $999,999	667	$732,628	$373	0.1%	$623	0.1%
$1,000,000 - $2,499,999	955	$1,639,807	$356	0.0%	$590	0.0%
$2,500,000 - $4,999,999	628	$3,536,797	$340	0.0%	$558	0.0%
$5,000,000 - $9,999,999	359	$6,877,614	$296	0.0%	$458	0.0%
$10,000,000+ receipts	203	$19,612,854	$251	0.0%	$357	0.0%
Establishments Not Operated Entire Year	517	$408,396	$373	0.1%	$623	0.2%

Source: 2012 Economic Census and ERG estimates.

Table 25 shows that under the second regulatory alternative, the one time costs per mammography facility would be $3,835 to $6,331. This is a modest reduction of between $144 and $265 compared with the proposed rule. This alternative does not include annual costs per facility. Firms in the small size class experience the smallest reduction in one-time costs compared with the proposed rule. For the smallest diagnostic imaging centers, one-time costs would be 25 percent of receipts.

Table 25: Small Business Costs as a Percentage of Receipts at Diagnostic Imaging Centers under Regulatory Alternative 2

Receipts Size	Number of Mammography Facilities	Average Receipts	One-time Cost	One-time Cost as a % of Receipts	Annual Cost	Annual Cost as a % of Receipts
<24,999	30	$15,356	$3,835	25.0%	$0	0%
$25,000 - $49,999	67	$38,616	$3,835	9.9%	$0	0%
$50,000 - $99,999	194	$74,934	$3,835	5.1%	$0	0%
$100,000 - $249,999	444	$169,203	$3,835	2.3%	$0	0%
$250,000 - $499,999	522	$367,015	$3,835	1.0%	$0	0%
$500,000 - $999,999	667	$732,628	$3,835	0.5%	$0	0%
$1,000,000 - $2,499,999	955	$1,639,807	$4,456	0.3%	$0	0%
$2,500,000 - $4,999,999	628	$3,536,797	$5,077	0.1%	$0	0%
$5,000,000 - $9,999,999	359	$6,877,614	$5,704	0.1%	$0	0%
$10,000,000+ receipts	203	$19,612,854	$6,331	0.0%	$0	0%
Establishments Not Operated Entire Year	517	$408,396	$3,835	0.9%	$0	0%

Source: 2012 Economic Census and ERG estimates.

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Technical Appendix

In this technical appendix, we summarize the potential impacts of the proposed MQSA rule on the federal budget. Because the rule may result in earlier detection of breast cancer, it can influence diagnosis and treatment services under Medicare and Medicaid, and ultimately increase the number of program beneficiaries who survive and subsequently incur routine lifetime medical expenses. To estimate these potential budget impacts, we analyze three different sets of outcomes: medical spending for additional ultrasound and biopsy procedures, reductions in cancer treatment costs for program beneficiaries, and the value of remaining lifetime and end-of-life medical expenses for averted deaths associated with the proposed rule. The overall budgetary impact is negative; the estimated reductions in cancer treatment costs are more than offset by increases in diagnosis testing and expected lifetime spending by survivors.

The analysis is summarized in the sections below. In the first section, we describe the insurance coverage data underlying each of the estimates in this analysis. The second explains the construction of the ultrasound and biopsy estimates. Treatment cost differences between early and late-stage cancer are detailed in the third section. In the fourth section, lifetime and end-of-life medical spending estimates are described. Finally, overall net budget impacts are presented in the fifth section.

Insurance Data

Information on Medicare and Medicaid insurance coverage is used throughout the analysis. These data are extracted from the 2007 to 2016 annual waves of the National Health Interview Survey. We use this data to construct a set of seven binary insurance coverage variables, each equal to the value of one if the survey respondent has that type of health insurance. If the respondent is not enrolled in that type of insurance, the variable is equal to zero. The insurance coverage variables are mutually exclusive, so a respondent cannot have a value of one for multiple coverage variables. These variables are:

- Only Medicaid
- Only Medicare
- Only private insurance
- Dual public insurance (Medicaid and Medicare)
- Public and private insurance (combination of private coverage with either Medicaid or Medicare)
- Triple coverage (combination of private coverage, Medicaid, and Medicare)
- Uninsured or other insurance coverage

Next, we estimate the average proportion of adult females (18 years and older) enrolled in each of the seven types of insurance coverage. This is done for each year of life, such that any given age is associated with a mean percentage of respondents insured under each of the seven coverage categories. For instance, 68 percent of 62-year-old females have only private health insurance coverage, 6 percent have Medicare, 6 percent have Medicaid, and the remaining 20 percent belong to the other four insurance categories. These estimates provide a good snapshot of both the number of women of a given age with public health insurance coverage, and how insurance coverage is expected to evolve with age.

Medical Spending for Additional Ultrasound and Biopsy Procedures

Age-specific estimates of insurance coverage are used to estimate Medicaid and Medicare spending for the additional ultrasound and biopsy procedures generated by the proposed rule. Because we lack information on the age distribution of women with breast cancer, we evaluate the public share of additional procedure spending under three assumptions. Under the first assumption, all women receiving an additional procedure are assumed to have insurance coverage reflecting a 62-year-old, or the median age of breast cancer diagnosis (Noone et al., 2018). This implies a relatively low level of public coverage. Under the second assumption, women are assumed to have insurance coverage associated with ages 66 and up. This reflects a high level of public coverage, as many women will have transitioned to Medicare. The third assumption is the average of the lower and upper-bound assumptions. We refer to this as the primary insurance coverage level.

To estimate the Medicare and Medicaid share of additional ultrasound and biopsy testing, we apply the insurance coverage estimates to the data used in the main analysis, above. Total annual costs for these procedures in the main analysis range from $19,604,964 to $41,110,994. For a lower-bound spending estimate, we multiply $19,604,964 by the proportion of women with public health insurance coverage, assuming those women are insured as if they are 62 years-old. For instance, the share of 62 year-old women with public insurance coverage (excluding the following 2 insurance categories, described above: only private insurance, and uninsured or other) is 17.3 percent. This yields a lower bound public spending estimate of just less than $3.39 million. We use a similar approach to construct the primary and upper bound estimates. The primary spending estimate is approximately $16.67 million, and the upper bound estimate is $35.47 million. Finally, we sum these values across the 10 years following the effective date of a final rule if the proposed rule is finalized, applying either a 3 or 7 percent rate of discount in each of the 10 years.

Table A summarizes estimates of the additional public spending for ultrasound and biopsy procedures generated by the proposed rule. Over the 10-year period following the effective date of a final rule if the proposed rule is finalized, the present discounted value of additional procedure spending ranges from $28.92 to $302.60 million at a 3 percent discount rate, and $23.81 to $249.16 million at a 7 percent discount rate. Our primary estimates of the present discounted value of additional procedure spending are approximately $142.24 million at a 3 percent discount rate and $117.12 million at a 7 percent discount rate. The annualized values of the primary estimates are approximately $16.67 million at either rate of discount.

Table A - Present Discounted Value of Additional Ultrasounds and Biopsies, 10 Years After Rule Effective Date (millions of 2017 dollars)

	Discount Rate	Low	Primary	High
Present Discounted Value of Additional Ultrasounds and Biopsies	3%	$28.92	$142.24	$302.60
	7%	$23.81	$117.12	$249.16
Annualized Value of Additional Ultrasounds and Biopsies	3%	$3.39	$16.67	$35.47
	7%	$3.39	$16.67	$35.47

Treatment Cost of Early and Late-Stage Breast Cancer

As discussed in the main analysis, the proposed rule is expected to result in more frequent diagnoses of early-stage breast cancer. This is expected to generate a reduction in public spending for breast cancer treatment. To determine the magnitude of this reduction, we use recent estimates of Medicaid and Medicare spending for the treatment of breast cancer, by cancer stage and in the 12 months following initial diagnosis (Subramanian et al., 2011; Trogdon et al., 2017; Vyas et al., 2017). For Medicare patients, the average spending difference between local and the average between regional and distant breast cancer is $32,704. For Medicaid, this difference is $22,434. We multiply these spending differences by the same set of low, primary, and high insurance coverage assumptions used in the previous section. This results in estimated cost reductions of $5,323 for the low coverage assumption, $15,758 for primary, and $26,192 for high coverage. Finally, we multiply these values by the estimated number of additional early stage cancer diagnoses in the 10 years following the effective date of a final rule if the proposed rule is finalized (estimated in the main analysis), applying either a 3 or 7 percent rate of discount in each of the 10 years.

Table B summarizes estimates of the reduced cancer treatment costs associated with the proposed rule. Over the 10-year period following the effective date of a final rule if the proposed rule is finalized, the present discounted value of reduced spending ranges from $14.23 to $146.80 million at a 3 percent discount rate, and $10.98 to $113.27 million at a 7 percent discount rate. Our primary estimates of the present discounted value of reduced spending are approximately $63.97 million at a 3 percent discount rate and $49.36 million at a 7 percent discount rate. The annualized values of the primary estimates are approximately $7.50 million at a 3 percent discount rate and $7.03 million at a 7 percent discount rate.

Table B - Present Discounted Value of Reductions in Cancer Treatment Costs, 10 Years After Rule Effective Date (millions of 2017 dollars)

	Discount Rate	Low	Primary	High
Present Discounted Value of Treatment Cost Reduction	3%	$14.23	$63.97	$146.80
	7%	$10.98	$49.36	$113.27
Annualized Value of Treatment Cost Reduction	3%	$1.67	$7.50	$17.21
	7%	$1.56	$7.03	$16.13

Remaining Lifetime and End-of-Life Medical Spending

The proposed rule is expected to result in averted deaths from breast cancer. These are women who would have died from cancer in the baseline, but survived cancer because of the proposed rule. Some of these avoided fatalities will likely be Medicare or Medicaid beneficiaries at the time of their diagnosis, at some point in their future, or both. Consequently, increased cancer survivorship due to the proposed rule has implications for public medical spending.

To estimate the Medicare and Medicaid share of remaining lifetime spending for cancer survivors, we estimate both future lifetime medical spending and end-of-life medical spending.

We then multiply these estimates by the insurance coverage information discussed in the sections above. Future lifetime medical spending is estimated using data from the 2005 to 2014 waves of the Medical Expenditure Panel Survey. From these data, we extract a sample of adult females. We then estimate age and insurance-specific mean medical expenditures, in the same way we estimated age-specific mean insurance coverage probabilities, above. In other words, for a given age we generate the average medical expenditures for survey respondents in each of the seven insurance categories.

Next, we calculate the expected value of public medical expenditures from the perspective of a 62-year-old woman. To do so, we multiply the age-specific public insurance coverage probabilities (this represents five of the seven insurance categories) by their corresponding age and insurance-specific expenditure estimates. These values are then summed and multiplied by the probability of surviving to the given age. This results in the expected value of public medical expenditures for a given age. The values for each age are then discounted at either 3% or 7% and then summed, from the age of 62 to 100, to generate the present value of remaining lifetime public medical spending for a 62-year-old woman.

The calculation of the present value of end-of-life medical spending is calculated in a similar fashion. First, we identified spending estimates in the last year of life from recent literature (Cubanski et al., 2016; De Nardi et al., 2016; and Liu et al., 2006). The average end-of-life spending estimate from these authors is $16,158 for Medicare patients, and $35,192 for Medicaid. These values are multiplied by the age-specific insurance coverage probabilities. We also multiply by the probability of dying before the next age, based on US Life Table data from Arias (2017). The values for each age are then discounted at either 3% or 7% and then summed, from the age of 62 to 100, to generate the total present value of expected end-of-life public spending for a 62-year-old woman. Summing these estimates with the estimates in the preceding paragraph provides the present value of public medical spending for each averted death. These values are $157,782 at a 3% rate of discount and $97,053 at a 7% rate of discount. Finally, we multiply these values by the estimated number of averted deaths in the 10 years following the effective date of a final rule if this proposed rule is finalized (estimated in the main analysis), applying either a 3 or 7 percent rate of discount in each of the 10 years.

Table C summarizes the public spending impacts for all averted deaths associated with the proposed rule. Over the 10-year period following the effective date of the rule, the present discounted value of additional spending after averted death ranges from $19.65 to $41.26 million at a 3 percent discount rate, and $8.76 to $18.40 million at a 7 percent discount rate. Our primary estimates of the present discounted value of additional spending after averted death are approximately $29.96 million at a 3 percent discount rate and $13.36 million at a 7 percent discount rate. The annualized values of the primary estimates are approximately $3.51 million at a 3 percent discount rate and $1.90 million at a 7 percent discount rate.

Table C - Present Discounted Value of Remaining Lifetime Medical Spending After Averted Death, 10 Years After Rule Effective Date (millions of 2017 dollars)

	Discount Rate	Low	Primary	High
Present Discounted Value Medical Spending After Averted Death	3%	$19.65	$29.96	$41.26
	7%	$8.76	$13.36	$18.40

Annualized Value of Medical Spending After Averted Death	3%	$2.30	$3.51	$4.84
	7%	$1.25	$1.90	$2.62

Net Budget Impacts

To calculate the overall impact of the proposed on public spending, we sum the estimated impacts in Tables A, B, and C. These net impacts are shown in Table D. Because the reduction in cancer treatment costs reduces spending, estimates from Table B are shown with negative signs in Panel B of Table D. Over the 10-year period following the effective date of a final rule if the proposed rule is finalized, the net present discounted value of additional public spending ranges from $34.33 to $197.07 million at a 3 percent discount rate, and $21.59 to $154.29 million at a 7 percent discount rate. Our primary estimates of the present discounted value of additional public spending are approximately $108.23 million at a 3 percent discount rate and $81.12 million at a 7 percent discount rate. The annualized values of the primary estimates are approximately $12.69 million at a 3 percent discount rate and $11.55 million at a 7 percent discount rate.

Table D - Present Discounted Value of the Net Impact on Medicare and Medicaid Spending, 10 Years After Rule Effective Date (millions of 2017 dollars)

	Discount Rate	Low	Primary	High
Panel A - Present Discounted Value of Additional Ultrasounds and Biopsies				
Present Discounted Value of Ultrasounds and Biopsies	3%	$28.92	$142.24	$302.60
	7%	$23.81	$117.12	$249.16
Annualized Value of Ultrasounds and Biopsies	3%	$3.39	$16.67	$35.47
	7%	$3.39	$16.67	$35.47
Panel B - Present Discounted Value of Reductions in Cancer Treatment Costs (sign change to indicate negative spending impact)				
Present Discounted Value of Treatment Cost Reduction	3%	($14.23)	($63.97)	($146.80)
	7%	($10.98)	($49.36)	($113.27)
Annualized Value of Treatment Cost Reduction	3%	($1.67)	($7.50)	($17.21)
	7%	($1.56)	($7.03)	($16.13)
Panel C - Present Discounted Value of Remaining Medical Spending After Averted Death				
Present Discounted Value Spending After Averted Death	3%	$19.65	$29.96	$41.26
	7%	$8.76	$13.36	$18.40
Annualized Value of Spending After Averted Death	3%	$2.30	$3.51	$4.84
	7%	$1.25	$1.90	$2.62
Panel D - Net Additional Public Spending				
Present Discounted Value of Net Impact on Public Spending	3%	$34.33	$108.23	$197.07
	7%	$21.59	$81.12	$154.29
Annualized Value of Net Impact on Public Spending	3%	$4.02	$12.69	$23.10
	7%	$3.07	$11.55	$21.97

References (papers unique to this Technical Appendix)

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