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

## Final Regulatory Impact Analysis
## Final 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 final rule under Executive Order 12866, Executive Order 13563, 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). The Office of Information and Regulatory Affairs has determined that this final 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 final 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 $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

### B. Summary of Benefits and Costs

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

The benefits and costs associated with this final 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 life years (LY). Under the VSL approach, the estimate of annualized benefits over 10 years ranges from $42.00 million to $232.69 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from $48.42 million to $266.09 million. Under the LY approach, the estimate of annualized benefits over 10 years ranges from $12.99 million to $66.90 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from $8.50 million to $37.96 million. Because there is uncertainty in the literature about the most appropriate method for analyzing reduced mortality for the population affected by this final 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 LY approach, which yields the lower-bound estimate of the two methods. Other benefits that we are not able to quantify include reduced cancer morbidity and improvements in the accuracy of mammography by improving quality control and strengthening the medical audit.

The costs of the final rule include costs to mammography facilities to comply with the requirements of the regulation and costs associated with supplemental testing and biopsies resulting from the breast density requirements. The estimate of annualized costs over 10 years range from $28.87 million to $45.42 million at a 7 percent discount rate with a primary value of $36.31 million. Using a 3 percent discount rate, the annualized costs range from $27.61 million to $44.16 million with a primary value of $35.05 million.

Table 1. Summary of Benefits and Costs in millions 2020 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 | | $12.99 | $232.69 | 2020 | 7% | 10 years | |
| | | | $8.50 | $266.09 | 2020 | 3% | 10 years | |
| | Annualized Quantified | | | | | 7% | | |
| | | | | | | 3% | | |
| | Qualitative | Improvements in the accuracy of mammography and better management of mammography facilities. | | | | | | |
| Costs | Annualized Monetized $/year | $36.31 | $28.87 | $45.42 | 2020 | 7% | 10 years | |
| | | $35.05 | $27.61 | $44.16 | 2020 | 3% | 10 years | |
| | Annualized Quantified | | | | | 7% | | |
| | | | | | | 3% | | |
| | Qualitative | | | | | | | |
| Transfers | Federal Annualized Monetized $/year | | | | | 7% | | |
| | | | | | | 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 $416-$727, which would represent a maximum of 1.2 percent of annual receipts | | | | | | | |

| | |
|---|---|
| | Wages: |
| | Growth: |

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

On March 28, 2019, FDA published a proposed rule to amend 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) (84 Federal Register 11669). We prepared a preliminary regulatory impact analysis (PRIA) for the proposed rule. In the paragraphs below, we describe and respond to the comments received on the PRIA. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

*(Comment 1)* Several comments mention there is a lack of benefit of density notification and that linking high breast density to additional imaging testing is not supported by evidence. These comments also mention that overdiagnosis and overtreatment should be addressed.

*(Response 1)* Recent research has shown that 7% to 11% of patients who are informed that they have dense breasts undergo supplemental ultrasound screening (Weigert and Steenbergen, 2012; Hooley et al., 2012; Saulsberry et al., 2019). Research studies have also shown that adjunct ultrasound screening in high-risk women with dense breasts results on average in the detection between 2.75 to 3.90 additional cancers per 1,000 women (Berg et al., 2008; Scheel et al. 2015; Houssami and Lee, 2018; Keating and Pace, 2019; Butler and Hooley, 2020). Because survival rates are higher for cancers detected at an earlier stage, early cancer detection due to supplemental screening such as ultrasound for women with dense breasts may result in a

reduction in cancer fatalities. We use this existing evidence to support our analysis related to quantified benefits of breast density reporting requirements. Additionally, the density notification requirement does not specify additional clinical management. We believe that a discussion of overtreatment and overdiagnosis of cancer is outside the scope of this analysis.

*(Comment 2)* A comment suggests that the analysis be revised to include distributional and equity effects.

*(Response 2)* FDA recognizes that distributional and equity considerations may exist as they relate to mammography practice and density notification. We have revised the distribution section of the FRIA to include a qualitative discussion of sociodemographic differences in mammography practice and outcomes.

### D. Summary of Changes

We have made edits to the analysis based on changes applied to the final rulemaking and the comments received outlined above. We extended the distributional effects section to discuss disparities across subpopulations and made minor updates for inflation. We have also updated several estimates with recent literature as well as industry and population data.

## II. Final Regulatory Impact Analysis

### A. Background

Mammography is an X-ray imaging examination used to identify signs of breast cancer. For patients 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 amending the mammography regulations that were issued under the MQSA and the FD&C Act. The MQSA establishes uniform baseline Federal standards designed to ensure that all patients 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 final rule would update the regulations by incorporating current science and mammography best practices.

FDA is making 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 federal regulations do not require that a notification of breast density be part of the report provided to the health care provider or of the lay summary be provided to the patient. However, there is increasing interest in breast density reporting. Thirty-eight States have passed laws mandating notification of breast density, although the laws impose requirements that vary from State to State. To ensure all patients receive breast density information from their mammograms, and that such required information is consistent, FDA is proposing to amend the mammography reporting requirements to require that the written report of the results of the mammographic examination which is provided to the health care provider and the lay summary

of the results that is 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 final 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 patients with dense breasts, in consultation with their healthcare providers, will likely choose to undergo additional screening. Additional screening of patients 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 December 2021, 38 States plus the District of Columbia 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, because 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 12 States without any density notification requirements. Furthermore, State laws impose requirements that vary from State to State, such that all patients 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 final 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.

### C. Purpose of the Final Rule

MQSA was enacted to ensure that all patients 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 not been amended since their inception, and the amendments in this final rule are designed to, among other things, address subsequent changes in mammography technology as well as 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 amending the mammography regulations to better address the protection of public health. These updates will 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.

## D. Baseline Conditions

The baseline for this analysis is determined by the current standard practice of mammography facilities and State-level density regulations as they relate to the provisions in the final rule. We consulted FDA's Division of Mammography Quality Standards (DMQS) and the Eastern Research Group (ERG) in determining the degree to which current standard practices align with provisions of the final rule. New requirements relating to statistics reporting are included in the final rule, as well as provisions that will 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 will also allow for

more precise categorization of mammography results and reflect the current practice of mammography. These changes will 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 December 2021, 38 States including the District of Columbia have passed legislation requiring information about breast density to be communicated to patients[1]. We assume that in the baseline the States currently without density reporting requirements would remain the same in the absence of this final rule[2].

## E. Benefits of the Final Rule

We consider the potential impact of the final rule on the accuracy of mammography as well as the impact of potential behavioral changes induced by the breast density notification requirements[3].

### 1. Accuracy of Mammography

The final rule will modify procedural requirements in several areas[4]. Such improvements in procedures might result in better quality control and management of mammography facilities.

[1] http://densebreast-info.org/legislation.aspx.
[2] 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 final rule. It is also possible that women living in States without reporting requirements undergo mammography at facilities 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.
[3] Our discussion of benefits is partially adapted from Section 5 of ERG's Final Report (2012a) and ERG's breast density addendum (2012b).
[4] We do not anticipate that this would lead to facility closures or reduction in services.

There are, however, no data with which to develop a quantitative estimate of the impact of such changes on public health.

This final 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. 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, 2012b). FDA is clarifying 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. Calculating and tracking the three audit metrics specified in the final rule will 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 final rule will ensure that patient and personnel records are made available to patients and personnel, respectively, 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 2 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 3 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.

Data from the Surveillance, Epidemiology, and End Results (SEER) Program (2021) yield estimates that there were 281,550 new female breast cancer cases diagnosed in 2021. Assuming that these diagnoses are accurate, this suggests up to 281,550 true positives each year. Approximately 10 percent of screening mammograms produce false-positive results (Brewer, et al., 2007; Nelson et al., 2016). As of July 1, 2022, there were approximately 39,329,133 total annual mammography procedures reported to FDA by MQSA accrediting bodies, based on facility-provided information (FDA, 2022). Agency data collected from the accreditation bodies, provided to them by facilities, indicate that approximately 76 percent[5] of the total procedures reported were screening mammograms, yielding a total of 29,890,141 exams. This suggests that there are approximately 2,989,014 (0.10 x 29,890,141) false positives a year in the initial screening.

The number of false negatives can be deduced from the sensitivity estimates as specified in Table 2. 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 356,392 (281,550 / 0.79). Subtracting the number of true positives (281,550) from the total condition positive cases (356,392) indicates that there are 74,842 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

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

there are 426,591 condition positives (281,550/ 0.66) and 145,041 false negative screening mammograms (426,591 – 281,550). Finally, subtracting the sum of true positive (281,550), false positive (2,989,014), and false negative (74,842 to 145,041) screening mammograms from the total number of screening mammograms (29,890,141) suggests between 26,474,536 and 26,544,735 true negative screening mammograms per year.

Table 2. 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 3. Screening Mammography Sensitivity and Specificity

| **79 Percent Sensitivity Estimate** | | | | |
|---|---|---|---|---|
| | | **True Condition** | | |
| | | **Positive** | **Negative** | **Sum** |
| **Test Outcome** | Positive | 281,550 | 2,989,014 | 3,270,564 |
| | Negative | 74,842 | 26,544,735 | 26,619,577 |
| | Sum | 356,392 | 29,533,749 | 29,890,141 |
| | Sensitivity | 79.0% | | |
| | Specificity | | 88.9% | |
| **66 Percent Sensitivity Estimate** | | | | |
| | | **True Condition** | | |
| | | **Positive** | **Negative** | **Sum** |
| **Test Outcome** | Positive | 281,550 | 2,989.014 | 3,270,564 |
| | Negative | 145,041 | 26,474,536 | 26,619,577 |
| | Sum | 426,591 | 29,463,550 | 29,890,141 |
| | Sensitivity | 66.0% | | |
| | Specificity | | 88.9% | |

Table 3 shows that screening mammography yields nearly 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 $144.14 and the total cost of a needle core breast biopsy and pathology is estimated to be $271.90 (Vlahiotis et al., 2018[6]). 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 patients.[7]

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 patients with breast cancer who have abnormal mammographic results).

Patients 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 (Sarveazad et al., 2018; American Cancer Society, 2019) 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 3 shows that screening mammography produces an estimated 74,842 to 145,041 false negatives each year. It is estimated that 25 percent of cancers in false negative mammograms are detectable (Yankaskas et al., 2001; Houssami and Hunter, 2017). This means that between 18,461 (25 percent of 74,842) and 35,777 (25 percent of 145,041) cancers that could be detected on screening mammograms annually are not. We are unable to estimate to

[6] Estimates were updated to 2020 dollars.
[7] For further discussion of the short-term anxiety caused by false positive mammograms, see Totson, et al. (2014).

what extent this final rule will affect the number of false negatives, but given the large health 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 patients with true positive screening mammograms may not lead to an accurate estimate of the potential reduction in morbidity and mortality for patients 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 patient 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 final 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 final mammography regulation, although the impact of these changes could not be quantified. Specifically, the final regulation requires facilities to retain mammograms for up to ten years and transfer them upon patient request; under the final rule, such requirements will 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 will 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 provisions, interpreting physicians will be better able to interpret exams.

2. Breast Density Notification Requirements

The final regulation includes provisions that will 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. The updated notification language in the final rule does not recommend supplemental imaging evaluation for patients with dense breasts, but rather provides a baseline of information for discussion between a patient and their healthcare provider. However, these provisions will likely result in supplemental screening for some high-risk 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 final rule. The benefits that are expected to result from this provision would be potential reductions in cancer treatment costs due to early cancer detection in high-risk women who decide to undergo supplemental screening after being fully informed of breast density information, as well as reductions in breast cancer mortality and morbidity. This final rule would enact a standard requirement that would ensure that all patients and providers receive complete and consistent breast density information in mammography reports.

**Affected Population and Health Gains**

As discussed above, there are 29,890,141 screening mammograms performed each year. Approximately 87 percent, or 26,004,423 (29,890,141 x 0.87), 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 10,661,813 and 12,222,079 normal mammograms show dense breasts each year. As of December 2021, 38 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 92.4 percent of the U.S. population, while 7.6

percent of women reside in States that do not require breast density information to be communicated to patients.[8] Assuming that mammograms are distributed among States proportionally according to population, approximately 814,420 (10,661,813 x 0.076) to 933,603 (12,222,079 x 0.076) 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 density notification requirements. The density reporting will likely lead to additional testing.[9] Some providers may recommend additional action 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 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 will likely cause increased numbers to follow through with any additional screening. However, not every patient with dense breasts would be advised to undergo supplemental screening, and not every patient advised to do so would do so. Several studies have been conducted on the utilization of ultrasounds for women with dense breasts. It is estimated that between 7 percent and 11 percent of patients who were advised to undergo supplemental screening ultrasound did undergo that

[8] https://data.census.gov/cedsci/table?q=EC1700&n=621512%3A622%3AN0300.62%3AN0600.62

[9] We note that the 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.

exam (Weigert and Steenbergen, 2012; Holley et al., 2012; Saulsberry et al., 2019).[10] 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 58,883 (814,420 x 0.07) and 103,163 (933,603 x 0.11) women would undergo supplemental ultrasound screening annually.

Adjunct ultrasound screening in high-risk women with dense breasts results on average in the detection between 2.75 to 3.90 additional cancers per 1,000 women (Berg et al., 2008; Scheel et al. 2015; Houssami and Lee, 2018; Keating and Pace, 2019; Butler and Hooley, 2020). Applying this rate to the number of women undergoing supplemental ultrasound screening results in 162 ((58,883/1,000) x 2.75) to 402 ((103,163/1,000) x 3.90) additional cancers detected annually as a result of the breast density notification provision, with a primary value of 266 ((79,885/1,000) x 3.33).

Some of the public health benefit from this final 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 screening 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

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

mammography screening alone, supplemental ultrasound screening for women with dense breasts would avert 0.36 additional breast cancer deaths per 1,000 women. Multiplying this fatality estimate by the number of women undergoing additional ultrasound screening per year yields 21 (0.36 x (58,883/1,000)) to 37 (0.36 x (103,163/1,000)) deaths per year that could be averted as a result of the breast density notification provision, with a primary estimate of approximately 29 (0.36 x (79,885/1,000)) 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, and the reduction in breast cancer deaths would begin 6 years after the effective date.[11] The full effects over a 10 year period correspond to a total of 1,133 to 2,816 early cancers detected with a primary estimate of 1,859. Total averted deaths at the full benefit level ranges from 85 to 149, with a primary estimate of 115. Tables 4 and 5 shows the stream of early cancers detected and averted deaths over a 10 year period.

Table 4. Total Early Cancers Detected Over a 10 Year Period

| Years after Effective Date of Rule (from 2024 to 2033) | Low | Primary | High |
|---|---|---|---|
| 1 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 |
| 4 | 162 | 266 | 402 |
| 5 | 162 | 266 | 402 |
| 6 | 162 | 266 | 402 |
| 7 | 162 | 266 | 402 |
| 8 | 162 | 266 | 402 |
| 9 | 162 | 266 | 402 |

[11] Our analysis assumes that supplemental testing will lead to early cancer diagnosis, such that in absence of the final 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.

| | | | |
|---|---|---|---|
| 10 | 162 | 266 | 402 |
| **Total** | **1,133** | **1,859** | **2,816** |

Table 5. Total Deaths Averted Over a 10 Year Period

| Years after Effective Date of Rule (from 2024 to 2033) | 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 | 21 | 29 | 37 |
| 8 | 21 | 29 | 37 |
| 9 | 21 | 29 | 37 |
| 10 | 21 | 29 | 37 |
| **Total** | **85** | **115** | **149** |

**a.** Reduced Cancer Mortality

We value avoided breast cancer deaths using two different methods: the average value of a statistical life and the value of life-years saved. The value per statistical life (VSL) approach uses a range of VSL estimates to measure the monetary 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 the Department of Health and Human Services (HHS) guidelines following the final rule's effective date (for the purpose of this analysis, we assume the rule to be effective in 2024) (HHS 2016). The estimates of VSL in 2020 dollars range from $5.5 million to $17.9 million, with a mid-point value of $11.8 million. VSL values in future years are adjusted for projected real income growth. The Congressional Budget Office (CBO) projects real income growth 0.8

percent per year through year 2051[12.] 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 life years (LY)[13]. We use this supplemental 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 LYs approach accounts for these age differences by estimating the expected future life-years for an age distribution specific to breast cancer patients. To generate these estimates, we use LY values from Sprague et.al (2015) and assume that supplemental screening would yield 2.1 additional LYs for each affected patient.

To monetize these estimated gains for premature deaths averted, we use estimates of the value per LY from the HHS guidelines referenced above. With the assumption that this rule will become effective in the year 2024, the value per LY in the first year ranges from $235,366 to $767,741 at a 3 percent discount rate and $398,215 to $1,298,938 at a 7 percent discount rate. We multiply the estimates for life years gained from an avoided death at the age of 62 by the value per LY and the overall number of avoided deaths in each year after the final rule takes

[12]. Congressional Budget Office. "The 2021 Long-Term Budget Outlook." Table A-2. Average Annual Values for Economic Variables That Underlie CBO's Extended Baseline Projections: Growth of Real Earnings per Worker, 2021-2051. https://www.cbo.gov/publication/57038#_idTextAnchor040. Accessed November 2022. (34)

[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.

effect. Finally, we adjust the results with 3 and 7 percent rates of discount and sum across each year of the 10 year period**.**

**b.** Reduced Cancer Morbidity

In addition to lower cancer mortality, the final 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 final 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 are unable to quantify and monetize these avoided costs due to limited information on health-related quality of life effects.

**c.** 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 detected attributed to the 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 costs in 2020 dollars are $40,533 at the local stage, $64,709 at the regional stage, and $79,973 at the distant stage. Because supplemental screening 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 $19,533 at 7 percent and $27,075 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

[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.

[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 2020 dollar values.

medical care for breast cancer are 66.2 hours per year in the initial phase and 185.9 hours per 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.

To quantify the opportunity cost of changes in time use for unpaid activities, we construct a range where the upper bound is the fully loaded mean hourly wage and the lower bound is the hourly value of time based on after-tax wages. Our primary estimate of the value of time is the average of the upper and lower bounds. The mean hourly wage in 2020 was $27.07[16]. We double this wage to yield a fully loaded wage of $54.14, which is our upper bound estimate of the value of time. To calculate the lower bound, we start with a measurement of the usual weekly earnings of wage and salary workers of $998.[17] We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.95. We adjust this hourly rate downwards by an estimate of the effective tax rate for median income households of about 17%, resulting in a post-tax hourly wage rate of $20.71. We estimate the value of time for changes in time use for unpaid activities ranges from $20.71 and $54.14, with a primary estimate of $37.43.

The estimated annual time costs per patient for each phase of care is $2,478 ($37.43 per hour x 66.2 hours) during the initial phase, $1,239 ($37.43 per hour x 33.1 hours) during the

[16] http://www.bls.gov/oes/current/oes_nat.htm

[17] U.S. Bureau of Labor Statistics. Employed full time: Median usual weekly nominal earnings (second quartile): Wage and salary workers: 16 years and over [LEU0252881500A], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/LEU0252881500A, June 9, 2022. Annual Estimate, 2021.

continuing phase, and $6,957 ($37.43 per hour x 185.9 hours) during the terminal phase.[18] We discount the estimates to account for the three year lag. This yields an average annual cost savings of $2,904 at a 7 percent discount rate and $3,256 at 3 percent.

**3.** Summary of Total Benefits

Table 6 summarizes the combined mortality and treatment costs savings associated with the final rule. When the mortality estimates are based on estimates calculated using the VSL, over a 10 year period, present discounted value of total benefits ranges from $295.01 million to $1.63 billion at a 7 percent discount rate, and $412.99 million to $2.27 billion at a 3 percent discount rate. Our primary estimates are $837.39 million at a 7 percent discount rate and $1.17 billion at a 3 percent discount rate. The annualized values of the primary estimates are $119.23 million at a 7 percent discount rate and $136.59 million at a 3 percent discount rate.

In Table 6 we also summarize combined mortality and treatment costs savings with mortality estimates calculated using the value of LY gained per averted death. Over a 10-year period, present discounted value of total benefits ranges from $91.26 million to $469.91 million at a 7 percent discount rate, and $72.50 million to $323.85 million at a 3 percent discount rate. Our primary estimates are $245.06 million at a 7 percent discount rate and $175.28 million at a 3 percent discount rate. The annualized values of the primary estimates are $34.89 million at a 7 percent discount rate and $20.55 million at a 3 percent discount rate.

Table 6. Total Benefits Over a 10 Year Period (in millions 2020 $)

| Scope | Description | Discount Rate | Low | Primary | High |
|---|---|---|---|---|---|
| **Mortality (VSL Approach)** | Present Discounted Value | 7% | $279.03 | $811.18 | $1,594.61 |
| | | 3% | $384.99 | $1,119.23 | $2,200.19 |
| | Annualized Value | 7% | $39.73 | $115.49 | $227.04 |
| | | 3% | $45.13 | $131.21 | $257.93 |

[18] The initial phase was defined as the first 12 months following diagnosis, and the last-year-of-life phase was defined as the final 12 months of life (Yabroff et al., 2007)

| | | | | | |
|---|---|---|---|---|---|
| **Mortality (LY Approach)** | Present Discounted Value | 7% | $75.28 | $218.84 | $430.20 |
| | | 3% | $44.49 | $129.35 | $254.27 |
| | Annualized Value | 7% | $10.72 | $31.16 | $61.25 |
| | | 3% | $5.22 | $15.16 | $29.81 |
| **Treatment Cost Savings** | Present Discounted Value | 7% | $15.98 | $26.22 | $39.71 |
| | | 3% | $28.00 | $45.93 | $69.58 |
| | Annualized Value | 7% | $2.28 | $3.73 | $5.65 |
| | | 3% | $3.28 | $5.38 | $8.16 |
| **Total Benefits (VSL Approach)** | Present Discounted Value | 7% | $295.01 | $837.39 | $1,634.32 |
| | | 3% | $412.99 | $1,165.17 | $2,269.77 |
| | Annualized Value | 7% | $42.00 | $119.23 | $232.69 |
| | | 3% | $48.42 | $136.59 | $266.09 |
| **Total Benefits (LY Approach)** | Present Discounted Value | 7% | $91.26 | $245.06 | $469.91 |
| | | 3% | $72.50 | $175.28 | $323.85 |
| | Annualized Value | 7% | $12.99 | $34.89 | $66.90 |
| | | 3% | $8.50 | $20.55 | $37.96 |

## F. Costs of the Final Rule

The estimated costs of this final rule include costs incurred by mammography facilities and the costs associated with supplemental testing and biopsies incurred by patients [19].

### 1. Mammography Facilities Costs

#### a. Affected Entities

As of July 1, 2022, FDA's data on registered facilities showed that there were 8,781 facilities certified to perform mammography, operating 24,122 mammography units (FDA, 2022). Mammography is performed in private practices, clinics, health maintenance organizations, and hospitals. For cost estimation, we have classified facilities as small (one unit),

[19] 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 final rule.

medium (two units), or large (three or more units). The distribution of affected entities by size is presented in Table 7.[20]

Table 7. Mammography Facilities by Size

| Size | Number of Mammography Units | Number of Establishments |
|---|---|---|
| Large | 3 or more | 996 |
| Medium | 2 units | 2,016 |
| Small | 1 unit | 5,769 |
| **Total** | | **8,781** |

b. Approach to Estimating Costs

Estimates for facility costs are based on a cost model derived by ERG. To estimate compliance levels and cost values, ERG visited and spoke with representatives of each type of affected entity. ERG also received input from the FDA's Division of Mammography Quality and Radiation Programs and project consultants. The costs to industry of complying with this final rule were estimated by identifying the incremental activities that will be required for new provisions, categorizing the provision according to the type of entity, and estimating how well current practices satisfy the requirements of each provision in the final regulation (ERG, 2012a). Representatives of each type of affected entity and FDA's DMQS was consulted in deriving current costs. We found that baseline practices in some cases came close to satisfying some of the new regulatory requirements. Under baseline practices, some facilities' practices would satisfy most of the new provisions without any changes, while virtually no facilities' practices would satisfy some of the new provisions. No incremental costs will be incurred for provisions that are currently satisfied by all facilities. Where applicable, the costs for each entity are

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

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 final rule will add to or clarify existing regulatory requirements but will not generate incremental costs. Additionally, many provisions will generate negligible incremental costs (or savings), such as minor revisions to administrative procedures. We are not anticipating that this final rule will lead to facility closures or reduction in services.

c. Facility Costs

The final rule will affect four types of staff members at mammography facilities: interpreting physicians, radiologic technologists, medical physicists, and administrative staff. The costs of complying with the final 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[21].

The final 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 will make the largest contribution to the estimated one-time costs of this final rule. We note that our cost estimate assumes that current forms are not in alignment with the final rule and that 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.

[21] Labor costs from ERG (2012a) were updated to 2020 wages and adjusted for benefits and overhead.

Several of the final provisions will lead to incremental annual costs for some mammography facilities.

*Provisions for transfer of records in the event the facility closes* – Facilities that close will 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 will be closing on an annual basis and apply closing costs to those facilities. Because mammography facilities will generally attempt to transfer records appropriately to another facility, we estimate that 75 percent of closing facilities will undertake the transfer without the regulatory requirement. We assume that the notification requirement for facility closure will 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 will be used to draft changes and then to circulate the procedures among the staff.

*Provisions to include breast density reporting in lay summary* – The final rule includes provisions requiring that the written report of the results of the mammographic examination provided to the healthcare 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 will 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 final 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 8 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 8. Mammography Facility Costs per entity (in millions 2020 $)

| | | 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 | $6 |
| 900.12(c)(1)(iv-vi) | Rewrite mammography report forms or insert new fields in electronic forms to allow for new assessment categories; add overall assessment of breast density | $6,134 | $4,897 | $3,672 | $0 | $0 | $0 |
| 900.12(c)(2)(iii-iv) | Include breast density reporting in lay summary | $1,127 | $902 | $676 | $0 | $0 | $0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 900.12(c)(4)(v) | Provide access to mammographic records if facilities are closed | $0 | $0 | $0 | $9 | $7 | $6 |
| 900.12(f)(1) | Record PPV, Cancer Detection Rate, Recall Rate | $168 | $271 | $309 | $398 | $637 | $716 |
| Total | | $7,429 | $6,069 | $4,658 | $416 | $651 | $727 |

Table 9. Aggregate Mammography Facility Costs (in millions 2020 $)

| Provision | Action | One-Time | Annual |
|---|---|---|---|
| 900.12(a)(4) | Make personnel records available upon request and upon facility closing | $0 | $55,682 |
| 900.12(c)(1)(iv-vi) | Rewrite mammography report forms or insert new fields in electronic forms to allow for new assessment categories; add overall assessment of breast density | $37,166,396 | $0 |
| 900.12(c)(2)(iii-iv) | Include breast density reporting in lay summary | $6,844,077 | $0 |
| 900.12(c)(4)(v) | Provide access to mammographic records if facilities are closed | $0 | $55,682 |
| 900.12(f)(1) | Record PPV, Cancer Detection Rate, Recall Rate | $2,496,452 | $5,807,650 |
| Total | | $46,506,925 | $5,919,015 |

Individuals from affected entities will need to devote time to reading and understanding this final rule. 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 3.5 hours. 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 other indirect costs. We estimate the time spent learning about the rule at a cost of $119.04 per facility (BLS 2020). Multiplying this estimate by the total number of mammography facilities yields a total one-time cost for reading the rule of $3,658,516.

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 breast density notification requirement. This final rule requires, among other things, that women with dense breasts be informed of their breast density in the lay summary report of the screening mammography, which will likely 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.[22] The costs related to this rule include the cost of supplemental ultrasound screening for women with dense breasts and the cost of unnecessary biopsies.[23]

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 $144.14 and the total cost of a needle core breast biopsy and pathology is estimated to be $271.90. 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 58,883 to 103,163 women with dense breasts receiving ultrasounds, we estimate the total annual cost of ultrasound screening of women with dense breasts is estimated to range from $8,487,187 to $14,869,685. 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

[22] 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.
[23] See Berg (2015) for additional discussion on additional costs that may arise as a result of supplemental screening, including the cost for screening MRI.

screening annually yields a total of 20,844 (354 x (58,883/1,000)) to 36,520 (354 x (103,163/1,000)) biopsies received. Multiplying this range by the average price of a biopsy yields the total cost of a biopsy ranging from $5,667,512 to $9,929,570. Adding the total cost of biopsies to the total costs of ultrasounds yields an annual cost ranging from $14,154,700 to $24,799,255, with a primary estimate of $19,203,367.

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[24]. We construct a range where the upper bound is the fully loaded mean hourly wage and the lower bound is the national mean wage of $20.71. The mean hourly wage in 2020 was $27.07[25]. Doubling this wage results in a fully loaded wage of $54.14, our upper bound estimate of the value of time. Our primary estimate of the value of time is the average of the upper and lower bounds ($37.43). Multiplying the range 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 $1,219,458 (58,883 x $20.71) to $5,585,253 (103,163 x $54.14). The time cost associate with additional biopsies is estimated to range from $431,688 (20,844 x $20.71) to $1,977,180 (36,520 x $54.14). The total annual time costs to patients range from $1,651,146 to $7,562,433, with a primary estimate of $4,048,031.

3. Summary of Total Costs

[24] Sources: https://www.insideradiology.com.au/breast-core-biopsy/
https://www.insideradiology.com.au/breast-ultrasound/
[25] http://www.bls.gov/oes/current/oes_nat.htm.

Table 10 shows total undiscounted costs. Present value and annualized costs are presented in Table 11. Present value costs over a 10 year period range from $202.75 million to $319.03 million at a 7 percent discount rate, and $235.48 million and $376.71 million at a 3 percent discount rate. Our primary estimates are $255.05 million at a 7 percent discount rate and $298.99 million at a 3 percent discount rate. The annualized cost values of the primary estimates are $36.31 million at a 7 percent discount rate and $35.05 million at a 3 percent discount rate.

Table 10. Total Undiscounted Costs (in millions 2020 $)

| **Type** | **One-time** | **Annual** | | |
|---|---|---|---|---|
| | | **Low** | **Primary** | **High** |
| Industry Cost-Mammography Facilities | $50.17 | $5.92 | $5.92 | $5.92 |
| Public Cost-Density Notification | $0.00 | $15.81 | $23.25 | $32.36 |
| **Total** | **$50.17** | **$21.72** | **$29.17** | **$38.28** |

Table 11. Present Value and Annualized Costs Over a 10 Year Period (in millions 2020 $)

| | Discount Rate | Low | Primary | High |
|---|---|---|---|---|
| | 7% | $202.75 | $255.05 | $319.03 |
| | 3% | $235.48 | $298.99 | $376.71 |
| | 7% | $28.87 | $36.31 | $45.42 |
| | 3% | $27.61 | $35.05 | $44.16 |

## G. Distributional Effects

We recognize that socioeconomic factors including race/ethnicity, income, education, and rurality exist in mammographic practice and breast cancer outcomes. These disparities are also present as it relates to breast density notification. Patients who are low income, lack health insurance coverage, or in certain racial or ethnic minority groups have been less likely to obtain screening mammograms (GAO 2006). Studies have also shown that minority patients are

diagnosed with breast cancer at more advanced stages (Smith-Bindman et al. 2006, Smigal et al. 2006, Shoemaker et al., 2018). Additionally, patients' understanding of mammography and preference for early detection of breast cancer have been shown to be influenced by differences in ethnic backgrounds (Jafri 2008). These studies suggest that there may be notable differences in how density notification may have been communicated to patients. This final rule would enact a standard requirement that would ensure that all patients and providers receive complete and consistent breast density information in mammography reports. In 2019, the latest year for which incidence data are available, in the United States, 20,450 new cases of breast cancer were reported among Black, Non-Hispanic women, and 6,600 Black, Non-Hispanic women died of this cancer. For every 100,000 Black, Non-Hispanic women, 128 new breast cancer cases were reported and 28 Black, Non-Hispanic women died of this cancer.[26] Health disparity and equity considerations may exist as they relate to mammography practice and density notification, and we acknowledge sociodemographic differences in mammography practice and outcomes. The final rule provides standard requirements that help to ensure that all patients and providers receive complete and consistent breast density information in mammography reports.

## H. International Effects

This final rule is based on mammography services performed domestically. We therefore do not expect effects outside of the United States or on international trade.

## I. Uncertainty and Sensitivity Analysis

[26] https://www.cdc.gov/cancer/breast/statistics/

Our analysis is sensitive to the number of States we assume would not have breast density reporting requirements in the absence of the final rule. There has been increasing interest in breast density at the State level over time. Since 2009, 38 States including the District of Columbia 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, the potential effects may be reduced.

J. Analysis of Regulatory Alternatives to the Final Rule

In our analysis of alternatives, we compare the total cost of the final rule with one option that would be less stringent and one option that would be more stringent. The first two alternatives would eliminate provisions in the final rule resulting in lower total costs, and the third 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 final rule relating to administrative procedures and personnel matters, such as establishing written cleaning procedures and documenting personnel information. [27] This alternative gives an example of the implications of including supplementary requirements that are not directly related to mammography practice.

Table 12 presents the undiscounted one-time and annual costs for each alternative and for the final rule. Table 13 shows the present value and annualized costs at 7 percent and 3 percent discount rates.

[27] These costs were also estimated by ERG.

Table 12. Total Costs of Alternatives (in millions 2020 $)

| Scope | One-time | Annual |
|---|---|---|
| **Alternative 1** | $6.15 | $21.72 |
| **Alternative 2** | $47.67 | $15.81 |
| **Alternative 3** | $52.02 | $21.97 |
| **Final Rule** | $50.17 | $21.72 |

Table 13. Present Value and Annualized Costs of Alternatives Over a 10 Year Period (in millions 2020 $)

| Scope | Discount Rate | Present Discounted Value | Annualized Value |
|---|---|---|---|
| **Alternative 1** | 7% | $158.74 | $22.60 |
| | 3% | $191.47 | $22.45 |
| **Alternative 2** | 7% | $158.68 | $22.59 |
| | 3% | $180.10 | $21.11 |
| **Alternative 3** | 7% | $206.32 | $29.38 |
| | 3% | $239.42 | $28.07 |
| | 7% | $202.75 | $28.87 |
| | 3% | $235.48 | $27.61 |

The first regulatory alternative, which excludes the density reporting requirements, would reduce the undiscounted one-time cost by $44.01 million. This option would substantially reduce the costs associated with the final regulation. However, this would eliminate any potentials benefits resulting from the breast density notification provision.

The second alternative only includes the provisions related to the breast density notification requirements. This option would reduce undiscounted one-time costs by $2.50 million and reduce annual costs by $5.92 million. Although this alternative would slightly reduce total costs, the full benefits of the final regulation would not be fully realized if the other provisions were excluded from the final 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 final rule that are administrative in nature. This option increases the one-time costs by $1.86 million, and increases the annual costs by $0.24 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 final regulation without corresponding medical benefits.

## III. Final 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 final 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 Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act[28].

### A. Description and Number of Affected Small Entities

Mammography facilities 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. Using the FDA's registration data, we estimate that there were 4,550 non-hospital facilities (all non-hospital entries), and 4,074 hospitals that performed mammography in 2011 (ERG, 2012a). Assuming

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

that hospitals account for the same proportion of mammography facilities in 2021, we estimate that there are 4,633 non-hospital facilities and 4,148 hospitals that perform mammography.

Data from the 2017 Economic Census provide a breakdown of facilities in these NAICS codes, by revenue size (U.S. Census Bureau, 2017). 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 14 and 15.

Table 14. Distribution of Revenues for Diagnostic Imaging Centers

| | Number of Establishments | Mammography Facilities |
|---|---|---|
| All Establishments | 6,318 | 4,633 |
| Establishments Operated for Entire Year | 5,479 | 4,018 |
| < $100,000 receipts | 381 | 279 |
| $100,000 - $249,999 receipts | 620 | 455 |
| $250,000 - $499,999 receipts | 660 | 484 |
| $500,000 - $999,999 receipts | 782 | 573 |
| $1,000,000 - $2,499,999 receipts | 1,245 | 913 |
| $2,500,000 - $4,999,999 receipts | 842 | 617 |
| $5,000,000 - $9,999,999 receipts | 598 | 438 |
| $10,000,000+ receipts | 351 | 257 |
| Establishments Not Operated Entire Year | 839 | 615 |

Sources: 2017 Economic Census and ERG estimates.

The Small Business Administration (SBA) size standard for small diagnostic imaging centers is annual receipts under $16.5 million.[29] Of the 4,018 mammography facilities projected to operate for the entire year, all but some of the 257 in the largest size category would be small

[29] Small Business Association. Table of Size Standards. Aug 19, 2019. Available from: https://www.sba.gov/document/support--table-size-standards

according to the 2019 size standard. Thus, a minimum of 3,760 of the mammography facilities in operation for the entire year, or 94 percent of the total, would be small.

Table 15. Distribution of Revenues for Hospitals

| | Number of Establishments | Mammography Facilities |
|---|---|---|
| All Establishments | 5,109 | 4,148 |
| Establishments Operated for Entire Year | 5,048 | 4,099 |
| < $2,500,000 receipts | D | D |
| $2,500,000 - $4,999,999 receipts | 56 | 45 |
| $5,000,000 - $9,999,999 receipts | 243 | 197 |
| $10,000,000+ receipts | 4,731 | 3,841 |
| Establishments Not Operated Entire Year | 61 | 50 |

Sources: 2017 Economic Census and ERG estimates.
Note: D - Withheld to avoid disclosing data for individual companies; data are included in higher level totals.

The SBA size standard for small hospitals is annual receipts under $41.5 million.[30] Of the 4,099 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 2019 size standard. Therefore, a minimum of 243 (the sum of all hospitals with less than $10 million in annual receipts), or 6 percent of the total, are small. In addition, an unknown number of the 3,841 hospitals with receipts of $10 million or more would be small.

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

We compiled the costs associated with the final rule and compared it to the estimated annual receipts of mammography facilities. Tables 16 and 17 present the calculations for diagnostic imaging centers and hospitals. The estimated one-time cost is $4,777 to $7,548 per facility, depending on its size classification. The estimated annual cost is $416 to $727 per facility.

[30] Small Business Association. Table of Size Standards. Aug 19, 2019. Available from: https://www.sba.gov/document/support--table-size-standards

Table 16: 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 |
|---|---|---|---|---|---|---|
| < $100,000 | 279 | $60,081 | $4,777 | 8.0% | $727 | 1.2% |
| $100,000 - $249,999 | 455 | $167,917 | $4,777 | 2.8% | $727 | 0.4% |
| $250,000 - $499,999 | 484 | $368,719 | $4,777 | 1.3% | $727 | 0.2% |
| $500,000 - $999,999 | 573 | $722,147 | $4,777 | 0.7% | $727 | 0.1% |
| $1,000,000 - $2,499,999 | 913 | $1,649,853 | $5,483 | 0.3% | $689 | 0.0% |
| $2,500,000 - $4,999,999 | 617 | $3,540,593 | $6,188 | 0.2% | $651 | 0.0% |
| $5,000,000 - $9,999,999 | 438 | $6,901,246 | $6,868 | 0.1% | $534 | 0.0% |
| $10,000,000+ receipts | 257 | $22,280,622 | $7,548 | 0.0% | $416 | 0.0% |
| Establishments Not Operated Entire Year | 615 | $497,382 | $4,777 | 1.0% | $727 | 0.1% |

Source: 2017 Economic Census and ERG estimates.

Table 17: Small Business Costs as a Percentage of Receipts at Hospitals

| Receipts Size | Number of Mammography Facilities | Avg Receipts | One-time Cost | One-time Cost as a % of Receipts | Annual Cost | Annual Cost as a % of Receipts |
|---|---|---|---|---|---|---|
| < $2,500,000 | D | D | $4,777 | D | $727 | D |
| $2,500,000 - $4,999,999 | 45 | $3,984,431 | $4,777 | 0.12% | $727 | 0.02% |
| $5,000,000 - $9,999,999 | 197 | $7,797,791 | $4,777 | 0.06% | $727 | 0.01% |
| $10,000,000+ | 3,841 | $210,607,801 | $6,171 | 0.00% | $598 | 0.00% |
| Establishments Not Operated Entire Year | 50 | $71,473,481 | | | | |

Source: 2017 Economic Census and ERG estimates.
Note: D - Withheld to avoid disclosing data for individual companies; data are included in higher level totals.

As shown in Table 16, one-time costs are 8 percent of receipts and annual costs are 1.2 percent of receipts for the smallest diagnostic imaging centers (those with annual receipts of less than $100,000). The final regulation will have smaller effects on hospitals because they provide more diversified services and tend to be larger. As shown in Table 17, in the smallest hospital size category for which we have receipts information, the one-time cost would be 0.12 percent of receipts and the annual cost would be 0.02 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 final rule on diagnostic imaging centers.

As shown in Table 18, under the first regulatory alternative, the one-time costs per mammography facility would be $287 to $428. This is a relatively large reduction of between $4,349 and $7,261 compared with the final rule. The annual costs per facility would be between $416 and $727, which is no change from the final rule. Firms in the small size class experience the smallest reduction in one-time costs compared with the final rule. For the smallest diagnostic imaging centers, one-time costs would be 0.07 percent of receipts and annual costs would be 1.2 percent of receipts.

Table 18: 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 |
|---|---|---|---|---|---|---|
| < $100,000 | 279 | $60,081 | $428 | 0.7% | $727 | 1.2% |
| $100,000 - $249,999 | 455 | $167,917 | $428 | 0.3% | $727 | 0.4% |
| $250,000 - $499,999 | 484 | $368,719 | $428 | 0.1% | $727 | 0.2% |
| $500,000 - $999,999 | 573 | $722,147 | $428 | 0.1% | $727 | 0.1% |
| $1,000,000 - $2,499,999 | 913 | $1,649,853 | $409 | 0.0% | $689 | 0.0% |
| $2,500,000 - $4,999,999 | 617 | $3,540,593 | $390 | 0.0% | $651 | 0.0% |
| $5,000,000 - $9,999,999 | 438 | $6,901,246 | $338 | 0.0% | $534 | 0.0% |
| $10,000,000+ receipts | 257 | $22,280,622 | $287 | 0.0% | $416 | 0.0% |
| Establishments Not Operated Entire Year | 615 | $497,382 | $428 | 0.1% | $727 | 0.1% |

Source: 2017 Economic Census and ERG estimates.

Table 19 shows that under the second regulatory alternative, the one-time costs per mammography facility would be $4,468 to $7,380. This is a modest reduction of between $168

and $309 compared with the final 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 final rule. For the smallest diagnostic imaging centers, one-time costs would be 7.4 percent of receipts.

Table 19: 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 |
|---|---|---|---|---|---|---|
| < $100,000 | 279 | $60,081 | $4,468 | 7.4% | $0 | 0% |
| $100,000 - $249,999 | 455 | $167,917 | $4,468 | 2.7% | $0 | 0% |
| $250,000 - $499,999 | 484 | $368,719 | $4,468 | 1.2% | $0 | 0% |
| $500,000 - $999,999 | 573 | $722,147 | $4,468 | 0.6% | $0 | 0% |
| $1,000,000 - $2,499,999 | 913 | $1,649,853 | $5,193 | 0.3% | $0 | 0% |
| $2,500,000 - $4,999,999 | 617 | $3,540,593 | $5,918 | 0.2% | $0 | 0% |
| $5,000,000 - $9,999,999 | 438 | $6,901,246 | $6,649 | 0.1% | $0 | 0% |
| $10,000,000+ receipts | 257 | $22,280,622 | $7,380 | 0.0% | $0 | 0% |
| Establishments Not Operated Entire Year | 615 | $497,382 | $4,468 | 0.9% | $0 | 0% |

Source: 2017 Economic Census and ERG estimates.

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