Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Devices and Radiological Health,

Complainant,

v.

Digital Radiology Center, Inc.,

Respondent.

Docket No. C-14-869
FDA Docket No. FDA-2014-H-0361

Decision No. CR3270

Date: June 24, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) initiated the above-captioned matter when it filed an Administrative Complaint for Civil Money Penalties (Complaint) dated March 24, 2014, with the Departmental Appeals Board, Civil Remedies Division (CRD), and FDA's Division of Dockets Management. CDRH alleged that Digital Radiology Center, Inc. (DRC), as well as three other Respondents, violated the Mammography Quality Standards Act of 1992 (MQSA or Act), codified at 42 U.S.C. § 263b, and the Act's implementing regulations. The Complaint sought to impose a $2,920,000 civil money penalty on DRC. Because DRC did not file a timely answer to the Complaint, and the Complaint alleges facts that are sufficient to prove violations of the Act for which a civil money penalty may be imposed, I am required under the regulations to issue an initial decision in default against DRC. Therefore, for reasons provided below, I impose a $2,920,000 civil money penalty on DRC.

I. Background and Procedural History

CDRH issued a Complaint dated March 24, 2014, that named the following as Respondents: DRC, Brigitte Alzate, Oscar Alzate, and William B. Smith, M.D.[1] Complaint ¶¶ 5-8. DRC received the Complaint on March 27, 2014. The Complaint alleged that DRC violated several provisions of the Act for which CDRH sought a civil money penalty of $2,920,000. On April 22, 2014, Respondents Oscar Alzate, Brigitte Alzate, and DRC filed, pro se, a joint request for an extension to file their respective Answers to the March 24, 2014 Complaint. In my Acknowledgment and Pre-hearing Order (Order) dated April 30, 2014, I granted a 30-day extension and set May 27, 2014, as the date on which Respondents would have to file their answers.

Respondent Oscar Alzate and Respondent Brigitte Alzate (the Alzates), through counsel, filed a joint answer on May 27, 2014, but that answer did not state that DRC had joined it. On June 3, 2014, DRC, through the same counsel representing the Alzates, filed an answer to the Complaint.

Counsel for CDRH filed a motion for a default judgment against DRC and, later, a motion that I strike the late answer that the counsel for the Alzates filed on DRC's behalf. Counsel for the Alzates opposed both motions arguing that he had mistakenly failed to file the answer on time and that based on his reading of the regulations, DRC's answer was only one day rather than six days late. DRC argues that this shows that exceptional circumstances exist for the late filing. CDRH disagrees that exceptional circumstances exist.

II. Jurisdiction

The Secretary for Health and Human Services may impose civil money penalties on facilities that conduct breast cancer screening or diagnosis through mammography activities. 42 U.S.C. § 263b(h)(3). The procedures in 21 C.F.R. pt. 17 apply to such cases. 21 C.F.R. § 17.1(h); *see also* 42 U.S.C. § 263b(h)(4). Those regulations require that an administrative law judge, qualified under the Administrative Procedure Act, be assigned to preside over any case initiated with the filing of a complaint. 21 C.F.R. §§ 17.3(c), 17.5(d). Under an agreement between FDA and the Departmental Appeals Board, CDRH filed its Complaint against DRC with CRD. Consequently, the CRD

[1] The CRD Director docketed each Respondent under a separate CRD docket number. Respondent Smith filed a timely answer to the Complaint and a motion to dismiss the Complaint as it pertained to him. By order dated June 6, 2014, I dismissed the Complaint against Respondent Smith (CRD Docket No. C-14-868). Respondent Brigitte Alzate (CRD Docket No. C-14-866) and Respondent Oscar Alzate (CRD Docket No. C-14-867) filed a timely joint answer to the Complaint. Therefore, this Initial Decision and Default Judgment does not apply to those three respondents.

director administratively assigned this case to me for adjudication. Therefore, I have jurisdiction over this matter.

III. Issues

1. Whether DRC filed a timely answer to the Complaint.

2. Whether CDRH alleged facts in the Complaint, which, if assumed to be true, would establish DRC's liability under 42 U.S.C. § 263b(h) for a civil money penalty.[2]

IV. Analysis

A. DRC did not file a timely answer to the Complaint.

As stated above, DRC received CDRH's complaint on March 27, 2014, and DRC and the Alzates jointly filed a pro se request for an extension of time to file their answers. I granted that motion in my April 30, 2014 Order and provided DRC and the Alzates with 30 additional days to file their answer. In the Order I established a filing deadline of May 27, 2014 for DRC, Brigitte Alzate, and Oscar Alzate to file their answers to the administrative complaint against them. I permitted DRC and the Alzates to answer the administrative complaint jointly so long as they affirmatively stated that they intended to jointly defend the complaint. I also notified Respondents that their answers must comply with the requirements in 21 C.F.R. §§ 17.9 and 17.31. Further, I warned Respondents that no other extensions would be granted and that a failure to file a timely answer could result in a default judgment. Order ¶2.

In order to initiate a civil money penalty action, CDRH must "serv[e] on the respondent(s) a complaint . . . ." 21 C.F.R. § 17.5(a). The regulations require that proof of service include "the name and address of the person on whom the complaint was served, and the manner and date of service . . . ." 21 C.F.R. § 17.7(b). CDRH submitted proof that it served the March 24, 2014 Complaint on DRC by certified mail on March 27, 2014. This method of service and proof of service is permissible. *See* 21 C.F.R.

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[2] CDRH also argues that DRC has not shown exceptional circumstances that would permit me to accept DRC's late filed answer. DRC disagrees. The question as to whether there are exceptional circumstances that would permit DRC to file a late answer is not presently before me because this decision is only concerned with whether I should issue an initial decision and default judgment. *See* 21 C.F.R. § 17.11(a)-(b). If DRC decides to contest this decision, it must do so by filing a motion to reopen this case, at which time DRC will have to prove that exceptional circumstances precluded DRC from filing a timely answer. *Id*. § 17.11(c). If DRC proves such circumstances existed, I may withdraw this initial decision and default judgment. *Id*. § 17.11(d).

§ 17.7(a)(1), (b)(2). Based on that date of service, DRC's Answer was due no later than April 26, 2014. *See* 21 C.F.R. § 17.9(a). However, the regulations permit an administrative law judge to grant "up to 30 additional days" beyond the original 30-day deadline. *Id.* § 17.9(c). Therefore, when I granted DRC and the Alzates a 30-day extension to file their answers by May 27, 2014, I gave them the maximum additional time to file an answer permitted under the regulations. *See* 21 C.F.R. 17.9(c).

Although the Alzates, through counsel, filed an answer on May 27, 2014, DRC was not a part of that answer. Counsel for the Alzates filed an answer for DRC on June 3, 2014;[3] however, that filing was clearly late.[4] Therefore, I find that DRC did not file a timely answer to the Complaint.

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[3] It has been exceeding unclear whether counsel for the Alzates is representing only the Alzates or both the Alzates and DRC. It appears that after securing an extension of time to file the answer, the Alzates retained Daniel Nicholas of the Nicholas Law Firm, P.A., in Tampa, Florida, to serve as their attorney. Mr. Nicholas filed pleadings prior to May 27, 2014, that indicated he may have been representing DRC in this proceeding. For example, on May 20, 2014, Mr. Nicholas filed an Opposition to Respondent Smith's Request for Official Recognition/Judicial Notice on behalf of Respondents Oscar Alzate, Brigitte Alzate, and DRC. On May 21, 2014, Mr. Nicholas filed a First Request for Judicial Notice on behalf of Respondents Oscar Alzate, Brigitte Alzate, and DRC. However, other pleadings were filed only on behalf of Oscar and Brigitte Alzate, with no indication that Mr. Nicholas represented DRC. For example, on April 30, 2014, he filed an Amended Motion for Extension of Time to Answer Administrative Complaint only on behalf of Oscar and Brigitte Alzate, not DRC. Most notably, on May 27, 2014, Mr. Nicholas filed an Answer on behalf of Oscar and Brigitte Alzate, but not DRC. My April 30, 2014 Order made clear that Respondents Oscar Alzate, Brigitte Alzate, and DRC could file a joint answer and jointly defend the matter if they chose to do so. Order ¶ 2. The Alzates, by filing a joint answer without DRC, indicated that they would not be defending the matter along with DRC. If Mr. Nicholas is actually representing DRC as well as both of the Alzates, as he now asserts, then it calls into question whether there is an impermissible conflict of interest that would disqualify Mr. Nicholas from serving as counsel for DRC. *See* Fla. R. of Prof. Conduct Rule 4-1.7(a). This is because Mr. Nicholas stated in the June 3, 2014 answer he filed on DRC's behalf that "DRC is the alter ego of Respondent Dr. Smith." Further, in the amended motion for an extension of time to file an answer, Mr. Nicolas stated that Respondent Smith, and not the Alzates owned DRC. Should Mr. Nicholas attempt any future representation of DRC before me, i.e., file a motion to reopen this case, Mr. Nicholas must show that he has been duly appointed as counsel for DRC by an individual with authority to make that decision for DRC, and that under Florida conflict of interest rules, he is ethically able to accept such an appointment. A failure to make such a showing may result in the rejection of filings.

[4] Once CDRH filed a motion for default, Mr. Nicholas subsequently responded on DRC's behalf and argued that the deadline for filing its Answer was actually June 2,

B. DRC is subject to default judgment and is liable for the civil money penalty sought in the Complaint.

If service of the complaint has been properly effected under the regulations and if a respondent does not file an answer within 30 days of service of the complaint, then:

> [T]he presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:
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> (1) The maximum amount of penalties provided for by law for the violations alleged; or
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> (2) The amount asked for in the complaint, whichever amount is smaller.

21 C.F.R. § 17.11(a). Further, a failure to file a timely answer means that "the respondent waives any right to a hearing and to contest the amount of the penalties and assessments" imposed in the initial decision. 21 C.F.R. § 17.11(b).

Therefore, in order to determine whether DRC is liable for a civil money penalty, I must review the facts alleged in the Complaint and determine if such facts, taken as true, would establish a legal basis for penalties to be imposed under the relevant statute.

The Complaint provides the following facts. The American College of Radiology, an FDA-approved accreditation body, notified DRC on June 3, 2011, that its accreditation under the Act was denied and recommended that DRC cease conducting mammograms. Complaint ¶ 20. On June 6, 2011, FDA notified DRC that it was no longer certified because it did not meet the Act's certification requirements and that it must cease performing mammography. Complaint ¶ 21.

2014, even though that is beyond the time permitted by regulation and contradicts the express deadline stated in my April 30, 2014 Order. According to DRC, because my April 30, 2014 order was mailed to DRC, an automatic five day extension was added pursuant to 21 C.F.R. § 17.30(c). I note that the April 30, 2014 Order did not give DRC a "period of time" to respond, *e.g.*, 30 days from the date of the order, but a date certain, *i.e.*, May 27, 2014. Nor was the deadline for a *response*, but rather for an answer to the Complaint, the deadlines for which are specifically governed in 21 C.F.R. § 17.9. Most notably, even if DRC is correct with regard to the June 2, 2014 deadline for it to file an answer, it failed to file its Answer by *that* deadline as well.

From September 6 to September 12, 2012, FDA inspectors conducted an unannounced inspection of DRC. The inspectors "confirmed that the DRC facility had performed mammography without the required MQSA certificate . . . ." Complaint ¶ 22. FDA determined that DRC "performed at least 1,730 mammograms without an MQSA certificate between June 8, 2011 (the date DRC received FDA's notification letter) and September 6, 2012 (the last day on which DRC performed mammograms), a period of at least 315 business days." Complaint ¶23.

Inspectors also determined "that DRC had failed to implement and document a quality assurance and quality control program that substantially complied with MQSA quality standards." Complaint ¶ 24. The inspectors documented 15 such violations. Inspectors also found documents in a shred bin that DRC was required to maintain by regulation. Complaint ¶ 25. CDRH later directed DRC to notify all patients that received mammography services from DRC between June 8, 2011 and September 6, 2012, that DRC had performed the mammograms without proper certification. Complaint ¶ 31.

CDRH alleged in the Complaint that DRC was not certified pursuant to the MQSA and that the inspection between September 6 and September 12, 2012 revealed that DRC violated 42 U.S.C. § 263b(b)(1) (certification requirement to perform mammography), § 263b(f) (substantial compliance with the Act), and § 263b(h)(2) (timely notification of patients). CDRH asked the CRD to impose the following civil money penalties based on the alleged violations of the Act:

- $10,000 for DRC's violation of 42 U.S.C. § 263b(b);
- $315,000 for DRC's violation of 42 U.S.C. § 263b(f) for 315 days ($1,000 per day of noncompliance); and
- $2,595,000 for DRC's violation of 42 U.S.C. § 263b(h)(2) with regard to 1,730 patients ($1,500 per patient not timely notified.

Complaint ¶ 42.

A mammography facility must have a valid certificate to perform mammography scans. 42 U.S.C. § 263b(b)(1). In order to be certified, a facility must be accredited by an accreditation body approved by the FDA. 42 U.S.C. § 263b(d)(1)(A)(iv); 21 C.F.R. § 900.11(a), (b)(1). FDA performs annual inspections of facilities certified to perform mammography to ensure the facility's compliance with the Act, including all of the "quality standards" set forth in 42 U.S.C. § 263b(f). 42 U.S.C. § 263b(g)(1)(E).

If upon inspection FDA determines that the quality of mammograms performed in a facility are inconsistent with the requirements in the Act, FDA may require the facility to notify patients who received mammograms at the facility of the deficiencies posing a risk, the potential harm, and any remedial steps to be taken. 42 U.S.C. § 263b(h)(2).

The Act permits FDA to impose civil money penalties if a facility does not comply with the standards set forth in the Act. 42 U.S.C. § 263b(h)(3). Relevant here, FDA may, among other things, impose a civil money penalty up to $11,000 for a facility's failure to obtain a certificate as required in 42 U.S.C. § 263b(b). *Id*. § 263b(h)(3)(A); 21 C.F.R. § 17.2. FDA may also impose a civil money penalty up to $11,000 for each day a facility fails to comply with the quality standards in 42 U.S.C. § 263b(f). 42 U.S.C. § 263b(h)(3)(B); 21 C.F.R. § 17.2. Finally, FDA may impose a civil money penalty up to $11,000 for each failure of a facility to notify a patient of risk as required in 42 U.S.C. § 263b(h)(2). *Id.* § 263b(h)(3)(C); 21 C.F.R. § 17.2.

Accepting the facts alleged in the March 14, 2014 Complaint as true, I conclude that those facts establish that DRC is liable under the Act. *See* 42 U.S.C. § 263b(b)(1), (f), (h)(2). I further conclude that CDRH's request to impose a $2,920,000 civil money penalty against DRC is permissible because it is less than the maximum penalty prescribed by law. *See* 42 U.S.C. § 263b(h)(3)(A)-(C); 21 C.F.R. § 17.11(a)(2).

V. Conclusion

Based on the foregoing, I conclude that DRC failed to file a timely answer to CDHR's Complaint and that the regulations require that I issue this initial decision of default judgment. Therefore, I direct that DRC pay a civil money penalty in the amount of $2,920,000 to CDRH or to any federal governmental department, agency or office that CDHR specifies. This initial decision becomes final and binding upon both parties 30 days after the date of its issuance. 21 C.F.R. § 17.11(b).

It is so ordered.

/s/
Scott Anderson
Administrative Law Judge