UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

UNITED STATES OF AMERICA ex rel.)JEFFREY H. LIEBMAN and DAVID M.)STERN, M.D.,)	
Relators,	Case No. 3:17-0
v.)	District Judge Campbell, Jr.
METHODIST LE BONHEUR)HEALTHCARE and METHODIST)HEALTHCARE-MEMPHIS HOSPITALS,)	Magistrate Jud Holmes
Defendants.	

CV-00902

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METHODIST'S ANSWER TO THE COMPLAINT IN INTERVENTION

Defendants Methodist Le Bonheur Healthcare and Methodist Healthcare-Memphis Hospitals (collectively, "Methodist") respond to the United States' Complaint in Intervention as follows:

1. Because the allegations in Paragraph 1 contain the government's characterization of this action and purport to state legal conclusions, no response is required. To the extent Paragraph 1 characterizes statutes or regulations, those statutes or regulations speak for themselves and are the best evidence of their content. Methodist denies that it violated the AKS or is liable for damages to the Medicare program.

2. Methodist admits that it executed multiple agreements with West to structure the parties' affiliation, which created a comprehensive cancer treatment center that expanded treatment for cancer patients in the mid-South. Methodist admits that it purchased certain assets and assumed certain leases from West as part of that affiliation. To the extent Paragraph 2 references or quotes documents, those documents speak for themselves and are the best evidence of their content. To

the extent Paragraph 2 makes allegations about a hypothetical "legal partnership," Methodist admits that Methodist and West never structured their affiliation as a "legal partnership" under Title 61 of the Tennessee Code. Methodist denies the remaining allegations in Paragraph 2.

3. Methodist admits that Methodist and West executed an APA, LEA, PSA, MSA, and Unwind Agreement as part of their affiliation. To the extent Paragraph 3 purports to characterize those agreements, those documents speak for themselves and are the best evidence of their content.

4. Methodist admits that it invested \$3.5 million in and loaned \$3.5 million to ACORN as part of its affiliation with West. Methodist denies that The West Clinic, PLLC held an ownership interest in ACORN. Methodist admits the remaining allegations of Paragraph 4.

5. Methodist admits that it purchased assets from West and invested in ACORN as part of its affiliation with West. Methodist admits that ACORN used a portion of Methodist's investment in an amount less than \$3.5 million to repay a debt or liability to Dr. Schwartzberg and to West. Methodist denies the remaining allegations of Paragraph 5.

6. Methodist lacks knowledge or information sufficient to form a belief as to truth of the allegations about patients' viewpoints, as alleged in the first sentence of Paragraph 6. Methodist admits that it purchased certain assets and assumed certain leases from West where West provided outpatient services. Methodist denies the allegations in the second and third sentences of Paragraph 6. Methodist admits that it experienced an increase in referrals for inpatient services from West under the parties' affiliation. Methodist lacks knowledge or information sufficient to form a belief as to allegations about West's patient referrals to other parties during an unspecified time period but states that West referred significant numbers of patients to Methodist for inpatient services prior to the affiliation. 7. As a nonprofit disproportionate share hospital ("DSH") that serves low-income and indigent populations, Methodist admits that it was eligible to participate in the Medicare 340B Drug Pricing Program and could purchase outpatient drugs at discounted prices. Methodist admits that it purchased certain assets and assumed certain leases from West where West provided outpatient services. Methodist admits that for former West locations that were part of the affiliation, Methodist billed some payors, including Medicare, for some services provided. Methodist lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 7 related to the alleged purchase of an unidentified "West outpatient location." Methodist denies the remaining allegations in Paragraph 7.

8. Methodist denies that it compensated West in exchange for the volume or value of referrals to Methodist or that it increased payments to West as a result of increased referrals from West.

9. Methodist denies the allegations in Paragraph 9.

10. Methodist denies the allegations in Paragraph 10.

JURISDICTION AND VENUE

11. Methodist admits the allegations of Paragraph 11.

12. Methodist admits the allegations of Paragraph 12 that venue is proper in this District. Methodist denies all other allegations in Paragraph 12.

PARTIES

13. Because the allegations in Paragraph 13 contain the Government's characterization of its claims, no response is required. To the extent a response is required, Methodist denies the allegations in Paragraph 13.

14. Methodist admits the allegations in the first and second sentences of Paragraph 14.Methodist denies the remaining allegations in Paragraph 14.

15. Methodist admits the allegations in Paragraph 15.

16. Methodist denies that West was obligated to provide management services prior to the effective date of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist admits the remaining allegations in Paragraph 16.

17. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17.

18. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18.

19. Methodist lacks knowledge or information sufficient to form a belief as to where Jeffrey Liebman currently resides. Methodist admits the remaining allegations in Paragraph 19.

20. Methodist lacks knowledge or information sufficient to form a belief as to where David Stern currently resides. Methodist admits that David Stern previously was the Executive Dean and Vice Chancellor at UTHSC. Methodist admits the allegations in the third sentence of Paragraph 20. Methodist denies that David Stern can properly serve as a relator in this action.

LEGAL AND REGULATORY FRAMEWORK

A. <u>The False Claims Act</u>

21-44. Because the allegations in Paragraphs 21–44 purport to state legal conclusions, no response is required. To the extent Paragraphs 21–44 characterizes statutes, regulations, or case law, those statutes, regulations, or case law speak for themselves and are the best evidence of their content.

B. <u>The Anti-Kickback Statute</u>

45-46. Paragraphs 45–46 purport to quote language from Form CMS 855A. To the extent Paragraphs 45–46 characterize Form CMS 855A, that document speaks for itself and is the best evidence of its content.

47. Because the allegations in Paragraph 47 purport to state legal conclusions, no response is required. To the extent Paragraph 47 characterizes statutes or regulations, those statutes or regulations speak for themselves and are the best evidence of their content.

48-50. Paragraphs 48–50 purport to quote language from Form CMS 855A and state a legal conclusion. To the extent Paragraphs 48–50 characterize Form CMS-2552, statutes, or regulations, Form CMS-2552 or those statutes or regulations speak for themselves and are the best evidence of their content.

51-53. Paragraphs 51–53 purport to quote language from Form CMS-855I. To the extent Paragraphs 51–53 characterize Form CMS-855I, that document speaks for itself and is the best evidence of its content.

54-57. Because the allegations in Paragraphs 54–57 purport to state legal conclusions, no response is required. To the extent Paragraphs 54–57 characterize statutes or regulations, those statutes or regulations speak for themselves and are the best evidence of their content.

58. Because the allegations in Paragraph 58 contain the United States' characterization of the Medicare program and its claims, no response is required. To the extent Paragraph 58 characterizes statutes or regulations, those statutes or regulations speak for themselves and are the best evidence of their content.

59-65. Because the allegations in Paragraphs 59–65 purport to state legal conclusions, no response is required. To the extent Paragraphs 59–65 characterize statutes, regulations, or other documents, those documents speak for themselves and are the best evidence of their content.

66. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66.

67-69. Paragraphs 67–69 characterize and purport to quote language from CMS Form 1500. To the extent Paragraphs 67–69 characterize CMS Form 1500, that document speaks for itself and is the best evidence of its content.

70. Paragraph 70 purports to quote language from an unidentified document. To the extent Paragraph 70 characterizes the unidentified document, that document speaks for itself and is the best evidence of its content.

71-75. Because the allegations in Paragraphs 71–75 purport to state legal conclusions, no response is required. To the extent Paragraphs 71–75 characterize statutes, regulations, or case law, those statutes, regulations, or case law speak for themselves and are the best evidence of their content.

76. Methodist admits the allegations in Paragraph 76.

77. Methodist admits the allegations in the first sentence of Paragraph 77. Methodist denies the allegations in the second sentence of Paragraph 77 but states that the proportion of adult oncology patients with Medicare as a primary payer varied by year between 2012 and 2018.

FACTUAL BACKGROUND AND ALLEGATIONS

78. Methodist admits the allegations in Paragraph 78.

79. As a nonprofit DSH that serves low-income and indigent populations, Methodist admits that it was eligible to participate in the Medicare 340B Drug Pricing Program. Methodist denies the remaining allegations in Paragraph 79.

80. Methodist denies that it did not provide outpatient oncology services as of 2011. Methodist admits the remaining allegations in Paragraph 80.

81. Methodist admits that its bone marrow transplant program had obtained accreditation by the Foundation for the Accreditation of Cellular Therapy prior to Methodist's affiliation with West and that the program moved from Methodist University Hospital to Baptist Memorial Hospital in 2011. Methodist denies the remaining allegations in Paragraph 81.

82. Methodist admits that it had an affiliation with UTHSC during its affiliation with West. Methodist denies the remaining allegations in Paragraph 82.

83. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first three sentences of Paragraph 83. Methodist admits the remaining allegations in Paragraph 83.

84. Methodist admits that West had approximately \$130 million in revenue in 2011, and admits the remaining the allegations in Paragraph 84.

85. Methodist admits the allegations in the first sentence of Paragraph 85. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 85.

86. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 86.

Methodist denies the allegations in Paragraph 87. 87.

88. Methodist admits the allegations in the first sentence of Paragraph 88. Methodist denies the allegations in the second sentence of Paragraph 88.

I. <u>METHODIST PARTNERS WITH WEST TO FORM THE WEST CANCER</u> <u>CENTER</u>

89. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 89.

90. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 90.

91. To the extent Paragraph 91 purports to state a legal conclusion, no response is required. Methodist lacks knowledge or information sufficient to form a belief as to the factual allegations in Paragraph 91.

92. To the extent Paragraph 92 characterizes statutes or regulations, those statutes or regulations speak for themselves and are the best evidence of their content. Methodist lacks knowledge or information sufficient to form a belief as to the factual allegations in Paragraph 92.

93. Because the allegations in Paragraph 93 purport to state legal conclusions, no response is required. To the extent Paragraph 93 characterizes or quotes statutes or regulations, those statutes or regulations speak for themselves and are the best evidence of their content.

94. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 94.

95. Methodist denies that Foley identified "irreducible AKS risk" in the proposed transaction or that it communicated that the structure that West proposed was intended to induce referrals from physician groups to hospitals. Methodist denies the allegations in the second sentence of Paragraph 95.

96. Methodist admits the allegations in the first two sentences of Paragraph 96. Methodist lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 96.

97. Methodist admits the allegations in Paragraph 97.

98. To the extent the first sentence of Paragraph 98 refers to documents, such documents speak for themselves and are the best evidence of their content. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 98.

99. Methodist admits that West expressed a preference that its physicians not become Methodist employees. Methodist denies the remaining allegations in Paragraph 99.

100. Methodist admits that West wanted the deal to permit the parties to unwind their affiliation in certain circumstances.

101. Methodist denies that West held an ownership interest in ACORN. Methodist admits that Dr. Schwartzberg invested in ACORN, which was a separate entity from West and which assisted West with clinical trials. Methodist admits that West expressed a desire in 2011 for Methodist to invest in ACORN as part of the parties' affiliation. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 101.

102. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 102.

103. Methodist admits that it was eligible to participate in the 340B program because it is a nonprofit DSH that serves low-income and indigent populations. The remaining allegations in Paragraph 103 purport to state legal conclusions for which no response is required. To the extent the remaining allegations reference or interpret a statute or regulation, such statute or regulation speaks for itself and is the best evidence of its content.

104. Methodist admits that Chris McLean was aware that Baptist had at one time been eligible to participate in Medicare's 340B Drug Pricing Program but had lost its eligibility when it closed its downtown Memphis hospital and no longer treated sufficient numbers of uninsured or low-income patients to be able to qualify for the program.

105. Paragraph 105 purports to refer to or characterize documents, which speak for themselves and are the best evidence of their content.

106. Methodist admits that the parties' affiliation agreements permitted West to terminate the parties' agreements with six months' prior written notice to Methodist. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 106.

Methodist admits the allegations in Paragraph 107. 107.

108. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 108 relating to advice Foley provided to West. Methodist admits that the parties obtained fair market value opinions as alleged in Paragraph 108.

109. Methodist admits that Le Bonheur Children's Hospital was not included as part of the PSA or any of the related agreements.

Methodist lacks knowledge or information sufficient to form a belief as to the truth 110. of the allegations in Paragraph 110 relating to West's "idea" for compensation and fees. Methodist denies that Gary Shorb or Chris McLean had committed to pay an overall compensation amount. Methodist admits that Erich Mounce thought that the preliminary estimate of the management fee did not sufficiently capture the value of management services to be provided by West. Methodist denies the allegations in the third sentence of Paragraph 110, as Methodist had told West that it would only pay fair market value for services West provided, and there was no agreement on some total amount that West expected to receive.

111. Methodist denies the allegations in Paragraph 111. Methodist expressed to West that its physicians should refer their patients wherever they believed the patients would receive the best care.

112. Paragraph 112 constitutes the government's characterization of documents, which documents speak for themselves and are the best evidence of their content. Methodist denies that all payments in the affiliation flowed to West.

113. Paragraph 113 constitutes the government's characterization of the PSA and Unwind Agreement, which are documents that speak for themselves and are the best evidence of their content. Methodist denies that West had a unilateral right to terminate the parties' affiliation.

114. Methodist admits that it invested in ACORN in December 2011. To the extent Paragraph 114 purports to characterize any agreement between Methodist, West, and the University of Tennessee, that agreement speaks for itself and is the best evidence of its content.

115. Methodist admits that Methodist and West never formed a "legal partnership" under Title 61 of the Tennessee Code. Methodist denies that a document attached to the PSA is the "only reference to the vision" the parties had for their affiliation. To the extent Paragraph 115 purports to quote an attachment to the PSA between the parties, that document speaks for itself and is the best evidence of its content.

116. Paragraph 116 constitutes the government's characterization of its own complaint, to which no response is required. The transaction documents speak for themselves and are the best evidence of their content.

Methodist and West Execute an Asset Purchase Agreement A.

Paragraph 117 constitutes the government's characterization of the APA, which is 117. a document that speaks for itself and is the best evidence of its content.

118. Methodist admits the allegations contained in the first sentence of Paragraph 118. The second sentence of Paragraph 118 constitutes the government's characterization of the APA, which is a document that speaks for itself and is the best evidence of its content. To the extent Paragraph 118 purports to state legal conclusions regarding the requirements for billing as hospital outpatient departments, no response is required.

119. Paragraph 119 constitutes the government's characterization of the APA, which is a document that speaks for itself and is the best evidence of its content.

120. Methodist denies the allegations in Paragraph 120. Methodist was eligible to participate in the Medicare 340B Drug Pricing Program before its affiliation with West.

Paragraph 121 constitutes the government's characterization of the APA, which is 121. a document that speaks for itself and is the best evidence of its content.

122. Methodist admits that in 2011 it obtained a fair market value opinion related to the fixed assets, leasehold improvements, and inventory to be purchased through the APA.

123. The first sentence of Paragraph 123 constitutes the government's characterization of the APA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies the allegations in the second sentence of Paragraph 123.

124. Methodist admits the allegations in Paragraph 124.

125. Paragraph 125 constitutes the government's characterization of the LEA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that it directly compensated West's physicians for clinical services, through the PSA or otherwise.

126. Paragraph 126 constitutes the government's characterization of the LEA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that the LEA terminated on December 31, 2018.

127. Paragraph 127 constitutes the government's characterization of the LEA, which is a document that speaks for itself and is the best evidence of its content.

128. Methodist admits the allegations in Paragraph 128. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Footnote 2.

129. The first sentence of Paragraph 129 constitutes the government's characterization of the PSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies the allegations made in the second sentence that no services were provided before 2012 and that Chris McLean changed the effective date of the PSA to "capture the discounts for the 340B Program." Methodist admits the remaining allegations in the second sentence of Paragraph 129.

130. Paragraph 130 constitutes the government's characterization of the PSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that it compensated West's physicians for professional services through the PSA.

131. Paragraph 131 constitutes the government's characterization of the LEA and PSA, which are documents that speak for themselves and are the best evidence of their content.

132. Paragraph 132 constitutes the government's characterization of the PSA, which is a document that speaks for itself and is the best evidence of its content.

133. Paragraph 133 constitutes the government's characterization of the PSA, which is a document that speaks for itself and is the best evidence of its content.

Methodist admits the allegations in the first sentence of Paragraph 134. The second 134. sentence of Paragraph 134 purports to characterize the terms of the PSA, which is a document that speaks for itself and is the best evidence of its content. Methodist admits that the total amount of compensation paid under the PSA changed during the parties' affiliation. The fourth and fifth sentences of Paragraph 134 constitute the government's characterization of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content. Methodist denies the allegations in the sixth sentence of Paragraph 134.

135. Paragraph 135 constitutes the government's characterization of the PSA, which is a document that speaks for itself and is the best evidence of its content. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained within the parenthetical in Paragraph 135.

136. Paragraph 136 constitutes the government's characterization of the PSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that the method of compensation and the wRVU rates to be paid under the PSA were not set in advance.

137. Methodist admits the allegations in Paragraph 137.

B. West Is Contracted To Provide Inpatient and Outpatient Management Services

The first and third sentences of Paragraph 138 constitute the government's 138. characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist admits that the MSA was sometimes referred to as the "co-management" agreement. The allegations in Footnote 3 constitute the government's characterization of a specific report, which is a document that speaks for itself and is the best evidence of its content.

The first, second, and fifth sentences of Paragraph 139 constitute the government's 139. characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. The third and fourth sentences of the Paragraph 139 constitute the government's characterization and quotation of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content.

140. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations related to the undefined term "the Foley model." Therefore, Methodist denies the allegations in Paragraph 140.

141. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 141. Therefore, Methodist denies the allegations in Paragraph 141.

142. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 142. Therefore, Methodist denies the allegations in Paragraph 142. Methodist denies that any valuator drafted its fair market value opinion to "match" a percentage of revenue of Methodist's oncology service line.

143. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 143. Paragraph 143 also constitutes the government's characterization of the MSA, which speaks for itself and is the best evidence of its content.

144. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 144 related to the undefined "fee calculation" or "two increases to the fees." Methodist admits that its former CFO, Chris McLean, confirmed to the government that Methodist's oncology service line was not limited to patients referred by West's physicians.

145. Methodist admits the allegations in the first sentence of Paragraph 145. Methodist admits that payment terms under the MSA still remained to be finalized in December 2011.

146. Methodist admits that the amount to be paid under the MSA was finalized in December 2011 after HAI was engaged to provide a fair market value opinion and that that amount was consistent with the fair market value opinion. The second, third, and fourth sentences of Paragraph 146 constitute the government's characterization of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content.

147. Paragraph 147, including Footnote 4, constitutes the government's characterization of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content.

148. Paragraph 148, including Footnote 5, constitute the government's characterization of the MSA and a fair market value opinion, which are documents that speaks for themselves and are the best evidence of their content. Methodist admits that the amount to be paid under the MSA was consistent with a fair market value opinion obtained from an independent third-party valuator.

149. Methodist denies the allegations in Paragraph 149. Because most of Methodist's oncology services were provided on an outpatient basis at the Cancer Center Sites, the vast majority of management fees related to management services at those Sites.

150. Paragraph 150 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

151. Methodist denies the allegations in Paragraph 151. The method of compensation and the maximum aggregate compensation available under the MSA were set in advance.

152. Paragraph 152 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

153. Methodist denies the allegations in Paragraph 153. The amount Methodist ultimately paid West under the MSA was based on West's performance of management services and its achievement of performance incentive goals and milestones.

154. Paragraph 154 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

155. Paragraph 155 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

156. Methodist admits that it paid West over \$27 million in management fees under the MSA during the parties' affiliation. Methodist denies the remaining allegations in Paragraph 156.

i. West Performed Extensive Management Services Under The MSA

157. Paragraph 157 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that the MSA designated any specific management services, including the services described below, as "major requirements" of the agreement.

158. Paragraph 158 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist admits that West was paid for managing Methodist's oncology service line. Methodist denies that it paid West twice for the same services.

159. Paragraph 159 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

160. Paragraph 160 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that Section 1.11 of the MSA required West to "provide extensive training and education" to Methodist. Section 1.11 of the MSA required West to assist Methodist in developing educational training materials and in training and educating employees working on the oncology service line. 161. Paragraph 161 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

162. Paragraph 162 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

163. Paragraph 163 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

164. Paragraph 164 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

165. Paragraph 165 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that Section 1.4 of the MSA required the medical directors "to perform the duties under the MSA." Section 1.4 of the MSA required West to determine what medical directors were necessary to improve the quality, efficiency, and effectiveness of Methodist's oncology service line and to determine whether and to what extent it would compensate each medical director.

166. Paragraph 166 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content.

ii. <u>The FMV Opinion For The MSA Was Based On The Management</u> <u>Services that West Would Provide</u>

167. Methodist denies that CMS or the government has ever required parties to obtain a fair market value opinion "to avoid running afoul of the AKS." Methodist admits that paying West remuneration that was fair market value for services provided would not violate the AKS. Methodist admits that the parties obtained a fair market value opinion relating to the MSA from HAI.

168. Methodist admits that Methodist and West provided HAI with information related to services to be provided under the MSA. Methodist lacks knowledge or information sufficient to form a belief as to the totality of information on which HAI based its fair market value opinion, which is a document that speaks for itself and is the best evidence of its content.

169. Methodist lacks knowledge or information sufficient to form a belief as to HAI's assumptions in drafting its fair market value opinion. To the extent Paragraph 169 purports to characterize HAI's fair market value opinion, that opinion is a document that speaks for itself and is the best evidence of its content.

170. Paragraph 170, including Footnote 6, constitute the government's characterization and quotation of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content.

171. Paragraph 171 constitutes the government's characterization of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content.

172. Paragraph 172 constitutes the government's characterization of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that the projected annual net revenue across the oncology service line included only revenues generated by West's physicians.

173. Paragraph 173 constitutes the government's characterization of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that HAI tied the number of expected medical directors to the number of Methodist hospital campuses or expected a medical director to be located at each campus. Methodist denies that HAI expected the medical directors to be compensated directly.

174. Paragraph 174 constitutes the government's characterization of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that HAI estimated that 6600 hours would be required to complete management services under the MSA.

175. Paragraph 175 constitutes the government's characterization of a fair market value opinion, which is a document that speaks for itself and is the best evidence of its content.

C. Methodist and West Executed an Unwind Agreement

176. Methodist denies the allegations in the first sentence of Paragraph 176. The second and third sentences of Paragraph 176 constitute the government's characterization of the Unwind Agreement, which is a document that speaks for itself and is the best evidence of its content.

177. Paragraph 177 constitutes the government's characterization of the Unwind Agreement, which is a document that speaks for itself and is the best evidence of its content.

D. West and UT Executed an Affiliation Agreement

Paragraph 178 constitutes the government's characterization of an affiliation 178. agreement, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that it was a party to the Affiliation Agreement between UT and West.

179. Paragraph 179 constitutes the government's characterization and quotation of an affiliation agreement, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that it was a party to the Affiliation Agreement between UT and West.

180. Paragraph 180 constitutes the government's characterization and quotation of a specific document, which speaks for itself and is the best evidence of its content.

181. Paragraph 181 constitutes the government's characterization of an affiliation agreement, which is a document that speaks for itself and is the best evidence of its content.

Methodist lacks knowledge or information sufficient to form a belief as to the truth of an allegation about the "goal" of an agreement executed by UT and West.

182. Paragraph 182 constitutes the government's characterization of an affiliation agreement, which is a document that speaks for itself and is the best evidence of its content.

183. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 183.

E. <u>Methodist Invested in and Loaned Money to ACORN</u>

184. Methodist admits that it invested \$3.5 million in and loaned \$3.5 million to ACORN through its wholly-owned affiliate Ambulatory Operations, Inc. in December 2011, and that Dr. Schwartzberg was the President and CMO of ACORN. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the first sentence of Paragraph 184. The second sentence of Paragraph 184 constitutes the government's characterization of an attachment to the PSA, which is a document that speaks for itself and is the best evidence of its content.

185. Methodist admits that ACORN supported clinical research including through clinical trials. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining the allegations in Paragraph 185.

186. Methodist admits that West sought that Methodist participate in its clinical research arm, ACORN, as part of Methodist and West entering into their affiliation. Methodist admits that it invested \$3.5 million in and loaned \$3.5 million to ACORN as a part of the affiliation with West. Methodist admits that its former CFO used the term "start up" when describing ACORN during his interview with the government.

187. Methodist admits that it invested \$3.5 million in and loaned \$3.5 million to ACORN as part of its affiliation with West.

188. Methodist admits that a portion of its investment would be used to pay back debt owed to Dr. Schwartzberg and to pay down accounts receivable payable to West. Methodist denies that it contributed \$3.5 million to Dr. Schwartzberg and West.

189. Methodist admits that Michael Choukas provided a valuation opinion related to ACORN in October 2011 and ultimately became its CEO in 2014. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 189.

190. Methodist denies the allegations in Paragraph 190. Mr. Choukas' valuation opinion was based on ACORN's pro forma financial projections, interviews with ACORN management, and net revenue and EBITDA information for the most comparable public companies in the Contract Research Organization industry, among other things.

191. Methodist admits that Lynn Field, Methodist's Vice President of Legal Services and Compliance, provided recommendations about Michael Choukas' valuation opinion but denies that Ms. Field raised substantive concerns about Mr. Choukas' methodology or conclusions. Ms. Field's recommendations primarily related to the formatting or structure of the opinion and to disclosing Mr. Choukas' qualifications as a valuation expert within the opinion. Methodist denies that no changes were made in response to Ms. Field's recommendations. Mr. Choukas supplemented his opinion shortly thereafter.

Methodist admits that ACORN did not turn an overall profit and sustained financial 192. losses following Methodist's investment. Despite those losses, ACORN maintained value, continued to repay its loan to Methodist, and eventually was sold to new owners. Methodist lacks knowledge or information sufficient to form a belief as to what is surprising to the government.

193. Methodist admits that during a subsequent capital raise by ACORN, Chris McLean expressed concerns about the Methodist Board's potential reaction to the ACORN investment given that ACORN has not performed according to past projections. Methodist denies the remaining allegations in Paragraph 193.

194. Methodist admits that it recovered a substantial portion of the amount of its loan to ACORN, as well as interest paid on that loan, but did not recover its full equity investment. Methodist denies that it "ultimately extricated" itself from its investment in ACORN.

195. Methodist denies the allegations in Paragraph 195. ACORN was a full-service clinical research organization that offered a full range of services for managing outsourced clinical trials in oncology and oncology-related diseases and had conducted studies in over 30 different types of cancer. ACORN was a recognized leader in oncology patient reported outcome studies.

* * *

196. Methodist admits that one goal of its affiliation with West was to improve outcomes for cancer patients by providing comprehensive cancer care that integrated inpatient and outpatient Methodist denies the remaining allegations in Paragraph 196. Methodist lacks services. knowledge or information sufficient to form a belief as to the truth of the allegations in Footnote 7.

II. THE MULTI-AGREEMENT STRUCTURE COMPLIED WITH THE AKS

197. Methodist admits that the parties sometimes referred to their working relationship as a "partnership" but denies that Methodist and West held themselves out as having a legal partnership. Methodist routinely refers to the qualified physicians with whom it works as its "partners." The remaining allegations in Paragraph 197 constitute the government's characterization of the parties' affiliation agreements, which are documents that speak for themselves and are the best evidence of their content.

198. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations about the government's knowledge. The remaining allegations in Paragraph 198 purport to state a legal conclusion to which no response is required. An arrangement such as the parties' affiliation, under which one party pays another party fair market value for the services provided, does not violate the AKS.

Paragraph 199 constitutes the government's characterization of the APA, LEA, and 199. PSA, which are documents that speak for themselves and are the best evidence of their content. Under the APA, Methodist purchased the assets of the West Cancer Center Sites at fair market value and legally converted them to outpatient departments of Methodist's hospitals. Methodist staffed the West Cancer Center Sites during the parties' affiliation.

200. Methodist lacks knowledge or information sufficient to form a belief as to allegations about West's principal place of business or how West advised the government. West compensated Methodist for overhead expenses related to its operation of non-affiliated locations.

201. Methodist admits that one goal of its affiliation with West was to improve cancer care and expand treatment for cancer patients in the mid-South. Methodist denies the remaining allegations in Paragraph 201.

202. Methodist denies the allegations in Paragraph 202. During the parties' affiliation, Methodist's adult oncology service line operated under the official name of The University of Tennessee West Cancer Center - A Member of the Methodist Healthcare Family, but it was sometimes referred to as the West Cancer Center.

203. Methodist denies the allegations in Paragraph 203. Methodist admits that the structure of the affiliation was designed to, and did, comply with applicable statutes and regulations.

Methodist Paid West the Fair Market Value for Management Services A. **Provided Under the MSA**

204. Paragraph 204 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that the parties intended for eighty percent of the Base Management Fees to be attributed to inpatient management.

205. Methodist admits the allegations in the first sentence in Paragraph 205 with respect to Methodist's representations to the government. Methodist lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 205 about West's representations to the government. Methodist admits that it paid West more than \$16 million under the MSA for the four years 2015 – 2018.

206. Methodist denies the allegations in Paragraph 206.

i. <u>West Provided Base Management Services At All the Locations In the</u> **MSA**

207. The first sentence of Paragraph 207 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist otherwise denies the allegations in Paragraph 207.

208. Methodist lacks knowledge or information sufficient to form a belief as to truth of allegations related to unidentified statements that individuals associated with West made to the government. Methodist denies that West failed to provide inpatient management services systemwide or in accordance with the terms of the MSA.

209. Methodist denies the allegations in Paragraph 209.

210. Methodist admits that Mr. McLean acknowledged that Methodist had inpatient cancer care at University but denies that he stated it was not fully staffed. Methodist admits that Germantown did not have a dedicated inpatient cancer unit prior to Methodist's affiliation with West and that PwC so stated.

211. Methodist denies the allegations in Paragraph 211. Methodist and West developed a comprehensive cancer center with the most significant inpatient services provided at Methodist University Hospital, which is located in downtown Memphis and not in a white, affluent suburb.

212. Methodist admits that Methodist North and Methodist South did not have dedicated inpatient cancer units. Methodist denies that West did not intend to manage inpatient cancer services on a system-wide basis. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 212.

213. Methodist lacks knowledge or information sufficient to form a belief as to the truth of what it is alleged to have been said in unidentified "Methodist internal documents." Methodist admits that, unlike other health systems in Memphis, Methodist operates hospitals in economically distressed areas with large numbers of Medicaid, self-pay, or indigent patients, including Methodist North and Methodist South. The remaining allegations in Paragraph 213 are denied.

214. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the unidentified statements alleged in Paragraph 214. Methodist admits that cancer patients requiring inpatient care typically were directed or transferred to Methodist University Hospital or Methodist Germantown, which provided more specialized oncology services, but denies that treatment of cancer patients at Methodist North or Methodist South only occurred as an accident or emergency.

215. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 215.

Methodist lacks knowledge or information sufficient to form a belief as to the truth 216. of what it is alleged to have been in unidentified "Methodist internal documents." If they exist, such documents speak for themselves and are the best evidence of their content.

217. Methodist denies the allegations in Paragraph 217.

218. Methodist denies the allegations in Paragraph 218.

219. Methodist denies the allegations in Paragraph 219.

220. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the unidentified statements alleged in Paragraph 220. Methodist denies that West did not provide inpatient management services to Methodist North.

221. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the unidentified statements alleged in Paragraph 221.

222. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations about unidentified data or unidentified statements in Paragraph 222. Methodist denies that West did not provide management services to Methodist North and Methodist South. Methodist denies that Dr. Schwartzberg and Dr. Tauer were the only West physicians who provided medical director services under the MSA.

223. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations in Paragraph 223 related to the undefined terms "sites of consideration," "West Clinic locations," or "were not mentioned." Methodist and West always intended to implement a fully integrated EMR system.

224. Methodist states that it accurately conveyed to companies that provided fair market value opinions the nature of management services intended by the parties and denies that it concealed or omitted information from any valuators. Methodist denies that West failed to provide inpatient management services to its adult oncology service line in accordance with the terms of the MSA.

225. Methodist denies the allegations in Paragraph 225.

ii. West Provided The Base Management Services The MSA Required

226. Methodist denies the allegations in Paragraph 226.

227. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the unidentified statements attributed to Dr. Tauer. The remaining allegations in Paragraph 227 mischaracterize the intent of the parties' arrangements, the MSA, and other documents, which speak for themselves and are the best evidence of their content. Methodist denies those allegations.

228. Paragraph 228 appears to be quoting from the minutes of the January 12, 2012 Operating Committee meeting, which minutes speak for themselves and are the best evidence of their content. Methodist admits the remaining allegations in Paragraph 228.

- 229. Methodist admits the allegations in Paragraph 229.
- 230. Methodist admits the allegations in Paragraph 230.

231. Paragraph 231 appears to be characterizing the minutes of the February 9, 2012 Operating Committee meeting and a related presentation, which documents speak for themselves and are the best evidence of their content. Methodist admits the allegations in the first three sentences of Paragraph 231. Methodist denies the remaining allegations in Paragraph 231, including Footnote 9.

232. Methodist denies the allegations in Paragraph 232.

233. Most of Paragraph 233 is not a factual allegation but statements characterizing the United States' investigation, to which no response is required. To the extent a response is required,

the allegations are denied. Paragraph 233 also characterizes a provision of the MSA, which document speaks for itself and is the best evidence of its content.

Methodist lacks knowledge or information sufficient to form a belief as to the truth 234. of whether West filed annual reports in 2012, 2013, or in previous years. Methodist denies that West did not provide Methodist with frequent reporting in 2012 and 2013 relating to the management services under the MSA.

235. Methodist denies the allegations in the first sentence of Paragraph 235. The second sentence of Paragraph 235 constitutes the government's characterization of its own investigation, to which no response is required. Methodist admits that the West Cancer Center Annual Reports for 2015 and 2016 provide substantial evidence of the management services provided by West under the MSA.

236. To the extent the first sentence of Paragraph 236 alleges that West's annual reports did not relate to the MSA or services provided under the MSA, that allegation is denied. Methodist admits the allegations in the second sentence of Paragraph 236.

Methodist denies the allegations in the first sentence of Paragraph 237. Methodist 237. admits that Methodist paid West for services rendered under the MSA during the years 2017 and 2018 and that Methodist was reimbursed by Medicare for claims for services performed in the outpatient clinics owned by Methodist.

Methodist denies that West did not provide management services during 2012 and 238. 2013 or that Methodist acknowledged such. Methodist lacks knowledge or information sufficient to form a belief as to the truth of unidentified acknowledgements from West. Paragraph 238 also characterizes a provision of the MSA, which document speaks for itself and is the best evidence of its content. Methodist denies the remaining allegations in Paragraph 238.

239. The first sentence of Paragraph 239 constitutes the government's characterization and quotation of a document, which speaks for itself and is the best evidence of its content. Methodist denies the remaining allegations in Paragraph 239.

240. Methodist denies that West did not begin providing management services for inpatient care at Methodist hospitals until May 2016. Methodist admits that West developed a hospitalist program in 2016. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 240.

Methodist denies the allegations in the first and second sentences of Paragraph 241. 241. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the unidentified statements attributed to Mr. Mounce.

242. Methodist denies the allegation in the first sentence of Paragraph 242. The second and third sentence of Paragraph 242 constitute the government's characterization of a presentation, which is a document that speaks for itself and provides the best evidence of its content. Methodist denies that West physicians were not involved in developing training materials and conducting training.

243. Methodist denies the allegations in Paragraph 243.

244. Most of Paragraph 244 is not a factual allegation but statements characterizing the United States' investigation, to which no response is required. Methodist denies the allegations in Paragraph 244, including those in Footnote 10.

iii. West Maintained Voluminous Documentation For Its Services And **Regularly Reported To Methodist About Its Management Services**

Methodist admits the allegations in the first two sentences of Paragraph 245. The 245. third sentence of Paragraph 245 purports to quote a specific document, which speaks for itself and is the best evidence of its content. Methodist denies that it "paid West monthly without question"

for the duration of the parties' affiliation. Methodist admits the remaining allegations in Paragraph 245.

Methodist denies that it never reviewed whether West was performing the services 246. for which it received the base management fee under the MSA. Methodist denies it never asked West for documentation of the work West performed given that Methodist was paying West for results and outcomes, which were documented. Methodist admits that the MSA was not a time and materials contract.

247 The first two sentences of Paragraph 247 constitute the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist admits the remaining allegations in Paragraph 247.

248. Methodist admits that Dr. Schwartzberg and Dr. Tauer were West shareholders who treated patients and participated in clinical trials and research. Methodist denies the remaining allegations in Paragraph 248.

Methodist denies the allegations in Paragraph 249. 249.

250. The first sentence of Paragraph 250 in part constitutes the government's characterization of the parties' affiliation agreements, which speak for themselves and are the best evidence of their content. Methodist denies that Dr. Tauer does not know that he provided medical director services under the MSA. The last sentence of Paragraph 250 constitutes the Government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that Dr. Tauer did not interact with Methodist during the term of the MSA.

251. Methodist denies that Mr. Mounce is the only individual with knowledge of the base management services provided by West. Methodist admits that Mr. Mounce worked with Methodist staff to address items relating to the MSA. Methodist lacks knowledge and information sufficient to form a belief as to the truth of the unidentified statements attributed to Mr. Mounce. Methodist denies the remaining allegations in Paragraph 251.

252. The first sentence of Paragraph 252 constitutes the government's characterization and quotation of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 252.

253. Methodist admits the allegations in the first sentence of Paragraph 253 that Mr. Mounce had duties for West. The second and third sentences of Paragraph 253 constitute the government's characterization of the LEA and MSA, which documents speak for themselves and are the best evidence of their own content. Methodist denies that Mr. Mounce could not be paid under the MSA.

Paragraph 254, including Footnote 12, states legal conclusions to which no 254. response is required. To the extent a response is required, those allegations are denied.

255. Paragraph 255 constitutes the government's characterization of the MSA, which is a document that speaks for itself and is the best evidence of its content. Methodist denies that it never monitored West's activities and services provided under the MSA.

256. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations about what West told the government. The remaining allegations in Paragraph 256 are denied. West provided significant documentation of the services it provided under the MSA.

257. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations about what West told the government. Methodist denies that West has no documentation showing the management services that it provided under the MSA.

258. Most of Paragraph 258 is not a factual allegation but statements characterizing the United States' investigation, to which no response is required. Methodist denies the allegations in Paragraph 258.

iv. <u>Methodist Knew West Provided All The Services The MSA Required And</u> <u>Provided the Valuators with the Information They Requested</u>

259. Methodist admits that it paid West the full amount of base management fees for 2012 and 2013. Methodist denies the remaining allegations in Paragraph 259.

260. Methodist denies that West was legally obligated to obtain an updated fair market value opinion but admits that the parties engaged both HAI and Altegra to provide fair market value opinions related to the MSA. Methodist denies the remaining allegations in Paragraph 260. To the extent the third sentence of Paragraph 260 purports to characterize a specific email, that email speaks for itself and is the best evidence of its content.

261. Methodist admits that revenue information was provided in response to data requests from the MSA valuators, including information related to Fayette, Extended Care, Methodist North, and Methodist South. Methodist denies the remaining allegations in Paragraph 261.

262. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations about what West told the government or about how West calculated professional collections numbers. Methodist also lacks knowledge or information sufficient to form a belief as to the truth of allegations related to unidentified "financials."

263. The first sentence of Paragraph 263 constitutes the government's characterization of meeting minutes, which speak for themselves and are the best evidence of their content. Methodist denies that the entire range of Altegra's initial analysis was \$1 million more than HAI's initial analysis. Methodist admits the remaining allegations in Paragraph 263.

264. Methodist denies that Altegra was not fully familiar with the MSA requirements or did not conduct an in-depth analysis as part of its valuation. The second and third sentences of Paragraph 264 constitute the government's characterization of an email from HAI, which is a document that speaks for itself and is the best evidence of its content.

265. Methodist denies the allegations in the first and second sentences of Paragraph 265. The third sentence of Paragraph 265 constitutes the government's characterization of a fair market value opinion, which speaks for itself and is the best evidence of its content.

266. Methodist admits the allegations in the first sentence of Paragraph 266. Methodist denies the allegations in the second and third sentences of Paragraph 266.

267. Methodist admits the allegations in Paragraph 267.

268. Methodist denies the allegations in Paragraph 268.

269. Methodist admits that West engaged Pinnacle to conduct a valuation. Methodist is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 269.

270. Methodist denies the allegations in Paragraph 270.

271. Methodist admits the allegations in Paragraph 271.

272. Methodist admits that West confirmed to Pinnacle the total amount of revenue for Methodist's oncology service line, including Methodist Le Bonheur. Methodist denies the remaining allegations in Paragraph 272.

273. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 273, including Footnote 13.

274. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations related to communications between West and Pinnacle, or the lack thereof. Methodist admits the remaining allegations in Paragraph 274.

275. Methodist admits the allegations in Paragraph 275.

276. Methodist denies the allegations in Paragraph 276.

277. Methodist denies the allegations in Paragraph 277.

278. Methodist denies the government's characterization of its representations related to the total amount of professional collections. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations related to representations made by West. Methodist denies the remaining allegations in Paragraph 278.

279. Methodist admits the allegations in Paragraph 279.

280. Methodist denies that the DRGs referenced in the MSA "have nothing whatsoever to do with" services that could be provided to oncology patients. Methodist denies that the valuators represented that they relied on the inpatient DRGs identified in the MSA to determine revenues. Methodist denies that the two individuals the government interviewed in 2021 did not have "any understanding" why the DRGs referenced in the MSA were included in the contract. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations related to representations made by West.

281. Methodist denies the allegations in paragraph 281.

282. Methodist denies the allegations in Paragraph 282.

283. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations related to the undefined term "formal amendment" or to the government's knowledge. Methodist denies that the parties never amended any terms of the MSA.

284. Methodist denies the allegations in Paragraph 284.

B. The Deal Documents Reflected an Appropriate Affiliation

285. The first two sentences of Paragraph 285 constitute the government's characterization of the APA and LEA, which speak for themselves and are the best evidence of their content. Methodist admits that under the APA it purchased assets from West, including leases related to Cancer Center Sites. Methodist admits that the West Cancer Center included services provided at the Cancer Center Sites and at Methodist hospitals and that the West Cancer Center also came to include the Margaret West Comprehensive Breast Center. Methodist admits that it paid West under the MSA for management services that West provided at the West Cancer Center and that the West Cancer Center was owned and staffed by Methodist during the parties' affiliation. Methodist denies the remaining allegations in Paragraph 285.

286. Methodist denies the allegations in Paragraph 286.

287. Methodist denies that it purchased the locations of all of the Cancer Center Sites. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 287.

288. The first sentence of Paragraph 288 constitutes the government's characterization of unidentified email communications from West employees to Methodist, which documents speak for themselves and are the best evidence of their content. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations about unidentified email communications or about the remaining allegations in Paragraph 288.

289. Paragraph 289 constitutes the government's characterization of unidentified "formal communications to third parties," including a "proposal sent to St. Bernards," which documents speak for themselves and are the best evidence of their content. Methodist admits that
Mr. Mounce served as the Administrator of Methodist's adult oncology service line under the MSA.

290. The first sentence of Paragraph 290 constitutes the government's characterization and quoting of a document, which speaks for itself and is the best evidence of its content. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 290, which relate to the government's not understanding that document.

291. Methodist denies the allegations in Paragraph 291.

292. Methodist admits that Dr. Tauer was a Medical Director under the MSA and provided services to Methodist in that capacity. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations about unidentified communications between the government, Dr. Tauer, and West's counsel.

293. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 293.

294. The first sentence of Paragraph 294 constitutes the government's characterization of the MSA, which speaks for itself and is the best evidence of its content. Methodist denies that the MSA required the Medical Directors to perform inpatient management services at Methodist hospital locations. Methodist admits that Mr. McLean stated that Methodist purchased certain of West's assets related to some of its outpatient locations as part of the parties' affiliation.

295. Methodist denies the allegation in the first sentence of Paragraph 295. Methodist admits that some leased employees continued to provide services to West. Methodist denies that it either paid West or failed to be reimbursed by West for services related to non-affiliated sites or work.

296. Methodist denies the government's mischaracterization of its response to the government's request for information related to inpatient management services. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second sentence of Paragraph 296.

Methodist denies that West "occupied" space that Methodist owned or leased 297. without providing services under the parties' affiliation agreements. Methodist admits the remaining allegations in Paragraph 297.

Methodist lacks knowledge or information sufficient to form a belief as to the truth 298 of the allegations contained in the first sentence of Paragraph 298 or of allegations about where "West could have located itself for corporate purposes."

299. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first and second sentences of Paragraph 299. Methodist admits that in an August 14, 2013 meeting, Mr. Mounce noted that the estimated capital expense for cancer programs at the sites downtown and the UTMG building were just over \$40 million. Methodist admits that it contributed for the renovation of the Wolf River building and that West purchased that building from Methodist as part of the unwind of the parties' affiliation. Methodist denies that that facility was a source of West inpatient referrals to Methodist. Footnote 14 constitutes the government's characterization of an Annual Report and an attachment to the PSA, which documents speak for themselves and are the best evidence of their content.

300. Methodist admits the allegations in paragraph 300.

301. To the extent Paragraph 301 purports to characterize the terms of Dr. Ballo's offer letter, that document speaks for itself and is the best evidence of its content. Methodist denies that all of Dr. Ballo's compensation for his positions with West and the UT West Cancer Center was

paid through the Cancer Mission Support Fund. Methodist admits the remaining allegations in Paragraph 301.

302. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations about why West and UTHSC hired Dr. Ballo or how Dr. Ballo was paid in full. Methodist admits that it paid Cancer Mission Support Funds to UTHSC and that a portion of Dr. Ballo's compensation was funded through the Cancer Mission Support Fund. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Footnote 15. Methodist denies the remaining allegations in Paragraph 302.

303. Methodist denies the allegations in Paragraph 303.

Methodist denies that Dr. Schwartzberg and Dr. Tauer were the only West 304. physicians who provided medical director services under the MSA. Methodist admits the remaining allegations in Paragraph 304.

305. Methodist denies the allegations in Paragraph 305.

306. Methodist denies the allegations in Paragraph 306.

307. Methodist denies the allegations in Paragraph 307.

III. **METHODIST DID NOT PAY WEST FOR PATIENT REFERRALS**

308. Methodist admits that its former CEO confirmed that he anticipated an increase in the volume of patient referrals from West during the parties' affiliation. Methodist denies that West was required to refer all of its patients with inpatient needs to Methodist or that West did so. Methodist denies that non-party Foley Lardner "marketed" the parties' affiliation or West's patient referral pattern. The remaining allegations in Paragraph 308 are denied.

Methodist lacks knowledge or information sufficient to form a belief as to the truth 309. of the allegations contained in Paragraph 309.

310. Methodist denies the allegations in Paragraph 310. Chris McLean was clear that *not* all of West's patients would be referred to Methodist under the affiliation.

311. Methodist denies the allegations in Paragraph 311.

312. Methodist admits the allegations in the third, fourth, fifth, and eighth sentences of Paragraph 312. Methodist admits that it was reimbursed \$6,983 for inpatient treatment provided to A.R. from February 13 to February 28, 2013. Methodist denies the allegations in the sixth and seventh sentences of Paragraph 312. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 312.

313. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first and second sentences of Paragraph 313. Methodist admits that West treated patient P.H. on an outpatient basis at Methodist in January and February 2012, for which Medicare paid \$2,573. Methodist admits the allegations in the fourth sentence of Paragraph 313. Methodist admits that Methodist treated patient P.H. for inpatient services on June 30 to July 1, for which Medicare reimbursed Methodist \$4,340, and that a West provider referred the patient for treatment. Methodist admits the allegations in the sixth, seventh, and eighth sentences in Paragraph 313. Methodist admits that Medicare reimbursed Methodist \$37,196 for these inpatient services. Methodist denies the remaining allegations in Paragraph 313.

314. Methodist denies the allegations in Paragraph 314, including Footnote 16.

315. Paragraph 315 constitutes the government's characterization of a specific email, which is a document that speaks for itself and is the best evidence of its content.

316. The first sentence of Paragraph 316 constitutes the government's characterization of specific meeting minutes, which is a document that speaks for itself and is the best evidence of

its content. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 316.

317. Methodist denies the allegations in Paragraph 317. Chris McLean explicitly told the government that "The majority of the activity, we didn't want patients to be inpatient. That was the goal."

318. Methodist denies the allegations in Paragraph 318, including the allegations in Footnote 17.

319. Paragraph 319 constitutes the government's characterization and quotation of specific documents, which speak for themselves and are the best evidence of their content. Methodist denies that it sought to incentivize the referral of patients for genetic testing.

320. Methodist denies the allegations in the first sentence of Paragraph 320. The second and third sentences of Paragraph 320 constitute the government's characterization and quotation of specific documents, which speak for themselves and are the best evidence of their content. Methodist admits that it was affiliated with Duckworth. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations about West's concerns or subjective feelings about Duckworth relative to other providers.

321. To the extent the allegation in Paragraph 321 refers to documentation, such documentation speaks for itself and is the best evidence of its convent. The allegations in Footnote 18 constitute the government's characterization of Relators' previous allegations and the status of its own investigation, to which no response is required.

322. Methodist denies the allegations in Paragraph 322. Methodist made clear that all physicians should refer their patients to wherever the patients would receive the best care.

Methodist denies that developing a gynecological oncology program to serve 323. cancer patients in Jonesboro, Arkansas constitutes an example of Methodist's willingness to compensate physicians for patient referrals. Methodist admits that Mr. Mounce was a leased employee under the LEA and that he sent a proposal to St. Bernards in 2012. The remaining allegations in Paragraph 323 constitute the government's characterization of that proposal, which is a document that speaks for itself and is the best evidence of its content.

324. Paragraph 324 constitutes the government's characterization and quotation of a written proposal, which is a document that speaks for itself and is the best evidence of its content. Methodist admits that the referenced proposal related to developing a better coordinated oncology service line whereby cancer patients would receive higher quality care more efficiently.

325. Paragraph 325 constitutes the government's characterization and quotation of meeting minutes, which is a document that speaks for itself and is the best evidence of its content.

IV. THE PARTIES SOUGHT TO IMPROVE CANCER CARE THROUGH THEIR AFFILIATION

326. Methodist admits the allegations in the first sentence of Paragraph 326. Methodist denies that it "made substantial capital expenditures and provided funding" that allowed West to continue to expand outside the parties' affiliation, including construction of the Margaret West Breast Cancer Center.

327. Methodist denies the allegations in Paragraph 327.

328. Methodist admits that its former CFO told the government that he recalled that Methodist obtained approximately \$50 million in savings during the final year of the parties' affiliation from discounts through the Medicare 340B Drug Pricing Program. Methodist denies the remaining allegations in Paragraph 328.

329. Methodist denies the allegations in Paragraph 329.

330. Methodist lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 330 related to "outpatient claims performed by West providers."

Methodist lacks knowledge or information sufficient to form a belief as to the 331. allegations in Paragraph 331 related to "outpatient services through West providers" and "inpatient claims from West's referrals."

332. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 332.

Methodist lacks knowledge or information sufficient to form a belief as to the 333. allegations in Paragraph 333.

Methodist admits the allegations in Paragraph 334. 334.

335. Methodist denies the allegations in Paragraph 335.

V. **THE PARTIES' AFFILIATION COMES TO AN END**

336. Methodist denies the allegations in Paragraph 336.

Methodist admits that the parties discussed reimbursement trends moving more 337. towards value-based care. Methodist denies the remaining allegations in Paragraph 337.

338. Methodist denies the allegations in the first sentence of Paragraph 338, which constitute the government's characterization of the parties' affiliation as compared to other, unidentified "business relationships." Methodist admits that the parties agreed for seven years on the overall goal of creating a comprehensive oncology service line to improve health outcomes and expand cancer treatment for cancer patients throughout the mid-South. Methodist admits the allegations in the second sentence of Paragraph 338. Methodist lacks knowledge or information sufficient to form a belief about allegations related to West's alleged disputes with UTHSC management. Methodist denies the remaining allegations in Paragraph 338.

339. Methodist denies that its affiliation with West and UTHSC was not formally properly documented. Methodist admits that it discussed with West and UTHSC amending the terms of the parties' affiliation during the course of that affiliation, including moving to a PC-based or other affiliation structure. Methodist admits that the parties unwound their relationship rather than amend the affiliation's structure. Methodist denies the remaining allegations in Paragraph 339.

340. Methodist lacks knowledge or information sufficient to form a belief as to the truth of allegations about the personal feelings or knowledge of West's principals. Methodist admits that Mr. Shorb retired in 2016. Methodist denies the remaining allegations in Paragraph 340.

341. Methodist admits that Mr. Ugwueke succeeded Mr. Shorb as Methodist's CEO. Methodist denies that West did not trust Mr. Ugwueke. Methodist denies the remaining allegations in Paragraph 341.

342. Methodist denies the allegations in Paragraph 342. Methodist denies that Mr. Ugwueke expressed concerns related to AKS compliance or insisted that West physicians become Methodist employees.

343. To the extent Paragraph 343 purports to characterize a specific email or letter, Methodist denies that characterization, and the email or letter speaks for itself and is the best evidence of its content. Methodist admits that it attempted to reach agreement with West in 2016 about how the affiliation should be structured moving forward. Methodist denies the remaining allegations in Paragraph 343.

344. Methodist admits that it was clear with West that West physicians should refer their patients to wherever they would receive the best care, including to other area hospitals. Methodist

further admits that West desired to remain an independent practice and that its doctors did not want to become employees of Methodist. Methodist denies the remaining allegations in Paragraph 344.

345. Methodist denies the allegations in Paragraph 345.

346. Methodist admits the allegations in Paragraph 346.

347. Methodist admits that on August 11, 2018, West's legal counsel sent a letter to Methodist dated August 10, 2018, stating that West intended to unwind the parties' affiliation.

348. Methodist denies that West purchased any assets from Methodist during the unwind for less than fair market value, including the Margaret West Comprehensive Breast Center. Methodist denies that the East Campus/Margaret West Comprehensive Breast Center were assets that Methodist had initially purchased from West. Methodist admits the remaining allegations in Paragraph 348.

349. Methodist admits the allegations in Paragraph 349.

350. Methodist admits that West purchased assets related to the Cancer Center Sites as part of the parties' unwind of their affiliation. Methodist denies the remaining allegations in Paragraph 350.

351. Methodist lacks knowledge or information sufficient to form a belief as to the truth of the vague allegation that "West went back to the business of running West." Methodist admits that West continued to operate under the West Cancer Center name after the parties' affiliation. Methodist denies the remaining allegations in Paragraph 351.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

FCA: Presentation of False Claims (31 U.S.C. § 3729(a)(1) and (a)(1)(A)

352. Methodist incorporates by reference the answers and denials in response to Paragraphs 1 through 351 of the Complaint in Intervention.

353-354. Methodist denies the allegations in Paragraphs 353–354.

355. Paragraph 355 states a legal conclusion to which no response is required.

356-359. Methodist denies the allegations in Paragraphs 356–359.

SECOND CAUSE OF ACTION

FCA: Using False Statements to Get False Claims Paid (31 U.S.C. § 3729(a)(1)(B))

360. Methodist incorporates by reference the answers and denials in response to

Paragraphs 1 through 359 of the Complaint in Intervention.

361-365. Methodist denies the allegations in Paragraphs 361–365.

THIRD CAUSE OF ACTION

FCA: False Record Material to Obligation to Pay (31 U.S.C. § 3729(a)(1)(G))

366. Methodist incorporates by reference the answers and denials in response to

Paragraphs 1 through 365 of the Complaint in Intervention.

367-369. Methodist denies the allegations in Paragraphs 367–369.

FOURTH CAUSE OF ACTION

FCA: Reverse False Claim (31 U.S.C. § 3729(a)(1)(G))

370. Methodist incorporates by reference the answers and denials in response to

Paragraphs 1 through 369 of the Complaint in Intervention.

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371-374. Methodist denies the allegations in Paragraphs 371–374.

PRAYER FOR RELIEF

Methodist denies that the United States is entitled to any relief, including the specific relief requested in the Complaint in Intervention's Prayer for Relief.

GENERAL DENIAL

Methodist denies each and every allegation in the Complaint that is not specifically addressed above.

DEFENSES

Methodist alleges the following defenses to the Complaint in Intervention without assuming the burden of proof where such burden is otherwise on the United States pursuant to applicable law. Methodist reserves the right to amend and/or supplement its defenses and assert counterclaims as more information becomes known during the course of discovery.

As separate defenses, Methodist states as follows:

1. Plaintiff's claims are barred, in whole or in part, by the applicable statute of limitations or statute of repose.

2. Relator Stern is barred from participating in or recovering from this action as a relator by the False Claims Act's first-to-file bar, 31 U.S.C. § 3730(b)(5).

3. Plaintiff's claims are barred to the extent any alleged injuries or damages are the result of acts or omissions committed, in whole or in part, by third parties over whom Methodist had neither control nor responsibility, and whose actions or inactions cannot be imputed to Methodist.

4. Plaintiff's claims are barred to the extent any alleged injuries or damages are the result of acts or omissions committed, in whole or in part, by any employee that was taken outside the scope of their duties and that was not authorized, condoned, or ratified by Methodist.

5. To the extent Plaintiff seeks damages and/or penalties above and beyond actual damages, such damages or civil penalties would be unconstitutional because they would be a violation of the Eighth Amendment of the United States Constitution and/or otherwise impermissible under governing laws.

6. Any damages claimed to have been sustained by the United States must be offset by the value of services provided by Methodist, and the costs avoided to the United States or any relevant governments.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Methodist demands trial by jury of all issues so triable.

Methodist reserves the right to raise any additional defenses, cross-claims, and third-party claims not asserted herein of which they may become aware through discovery or other investigation.

Dated this 17th day of May, 2022.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been served upon counsel, via the Court's CM/ECF e-mail notification system, on this the 17th day of May, 2022:

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