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 11 *Palo Alto Medical Foundation*

12 UNITED STATES DISTRICT COURT
 13 NORTHERN DISTRICT OF CALIFORNIA
 14 SAN FRANCISCO DIVISION

15 UNITED STATES OF AMERICA *ex rel.*
 16 KATHY ORMSBY,

17 Plaintiff,

18 v.

19 SUTTER HEALTH and PALO ALTO
 MEDICAL FOUNDATION,

20 Defendants.
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Case No. 3:15-cv-01062-LB

Assigned to Hon. Laurel Beeler

DEFENDANTS' ANSWER TO UNITED STATES' COMPLAINT-IN-INTERVENTION

1 Defendants Sutter Health (“Sutter”) and Sutter Bay Medical Foundation dba Palo Alto
2 Medical Foundation (“PAMF”) (collectively, “Defendants”), by and through their counsel,
3 hereby answer and state their defenses and affirmative defenses to the United States’ Complaint-
4 In-Intervention (“Complaint”). Defendants generally allege that they have at all times acted
5 lawfully, in compliance with all applicable requirements of law, including, without limitation,
6 the Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7b(b) (“AKS”), the False Claims Act, 31 U.S.C.
7 §§ 3729-32 (“FCA”), and the California False Claims Act, Gov’t Code §§ 12650 *et seq.*
8 Defendants contend that they never knowingly presented or caused to be presented any false
9 claim or payment or made a false statement or record to cause a false claim to be paid or
10 approved, and that they are not therefore liable to Plaintiffs, or any other person or entity in
11 connection with the facts and causes of action asserted in the Complaint. Except as expressly
12 admitted herein, all allegations in the Complaint are denied. Defendants state as follows:

13 **INTRODUCTION**

14 1. Paragraph 1 contains no allegations with respect to a particular Defendant or
15 claim, and therefore no response is required. However, to the extent Paragraph 1 purports to
16 summarize and/or describe the provisions of the Medicare program, Defendants state that the
17 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
18 Paragraph 1 vary therefrom or with other applicable statutory or decisional law, Defendants deny
19 those allegations.

20 2. Paragraph 2 contains no allegations with respect to a particular Defendant or
21 claim, and therefore no response is required. However, to the extent Paragraph 2 purports to
22 summarize and/or describe the provisions of the Medicare program, Defendants state that the
23 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
24 Paragraph 2 vary therefrom or with other applicable statutory or decisional law, Defendants deny
25 those allegations.

26 3. Paragraph 3 contains no allegations with respect to a particular Defendant or
27 claim, and therefore no response is required. However, to the extent Paragraph 3 purports to
28 summarize and/or describe the provisions of the Medicare program, Defendants state that the

1 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
2 Paragraph 3 vary therefrom or with other applicable statutory or decisional law, Defendants deny
3 those allegations.

4 4. Paragraph 4 contains no allegations with respect to a particular Defendant or
5 claim, and therefore no response is required. However, to the extent Paragraph 4 purports to
6 summarize and/or describe the provisions of the Medicare program, Defendants state that the
7 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
8 Paragraph 4 vary therefrom or with other applicable statutory or decisional law, Defendants deny
9 those allegations.

10 5. Defendants admit that Sutter, through its provider affiliates, including PAMF,
11 furnishes healthcare services to thousands of Part C beneficiaries. To the extent Paragraph 5
12 purports to summarize and/or describe the provisions of the Medicare program, Defendants state
13 that the Medicare statute and regulations speak for themselves, and to the extent that the
14 allegations in Paragraph 5 vary therefrom or with other applicable statutory or decisional law,
15 Defendants deny those allegations.

16 6. Defendants admit that Sutter and PAMF entered into capitated arrangements with
17 some Medicare Advantage (“MA”) Organizations. To the extent Paragraph 6 purports to
18 summarize and/or describe the provisions of the Medicare program, Defendants state that the
19 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
20 Paragraph 6 vary therefrom or with other applicable statutory or decisional law, Defendants deny
21 those allegations. Defendants deny the remaining allegations in Paragraph 6.

22 7. Paragraph 7 states legal conclusions to which no response is required. Defendants
23 deny the remaining allegations in Paragraph 7.

24 8. Defendants deny all allegations in Paragraph 8.

25 9. Defendants deny all allegations in Paragraph 9.

26 10. Defendants deny all allegations in Paragraph 10.

27 11. Defendants deny all allegations in Paragraph 11.

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THE FALSE CLAIMS ACT

19. Paragraph 19 states legal conclusions and contains no allegations with respect to a particular Defendant or claim, and therefore no response is required.

20. Paragraph 20 states legal conclusions and contains no allegations with respect to a particular Defendant or claim, and therefore no response is required.

21. Paragraph 21 states legal conclusions and contains no allegations with respect to a particular Defendant or claim, and therefore no response is required.

22. Paragraph 22 states legal conclusions and contains no allegations with respect to a particular Defendant or claim, and therefore no response is required.

23. Paragraph 23 states legal conclusions and contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 23 purports to summarize and/or describe the provisions of the Medicare program, Defendants state that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 23 vary therefrom or with other applicable statutory or decisional law, Defendants deny those allegations.

24. Paragraph 24 states legal conclusions and contains no allegations with respect to a particular Defendant or claim, and therefore no response is required.

25. Paragraph 25 states legal conclusions and contains no allegations with respect to a particular Defendant or claim, and therefore no response is required.

26. Paragraph 26 states legal conclusions and contains no allegations with respect to a particular Defendant or claim, and therefore no response is required.

THE MEDICARE ADVANTAGE SYSTEM AND THE ROLE OF PROVIDERS

27. Paragraph 27 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 27 purports to summarize and/or describe the provisions of the Medicare program, Defendants state that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 27 vary therefrom or with other applicable statutory or decisional law, Defendants deny those allegations.

1 28. Defendants admit that MA Organizations contracted with Sutter and PAMF to
2 furnish healthcare services under MA plans. To the extent Paragraph 28 purports to summarize
3 and/or describe the provisions of the Medicare program, Defendants state that the Medicare
4 statute and regulations speak for themselves, and to the extent that the allegations in Paragraph
5 28 vary therefrom or with other applicable statutory or decisional law, Defendants deny those
6 allegations. Defendants deny all remaining allegations in Paragraph 28.

7 29. The allegation in Paragraph 29 that Sutter and PAMF are classified as “first tier”
8 and “related entities” pursuant to Medicare regulations is a legal conclusion to which no response
9 is required. To the extent Paragraph 29 purports to summarize and/or describe the provisions of
10 the Medicare program, Defendants state that the Medicare statute and regulations speak for
11 themselves, and to the extent that the allegations in Paragraph 29 vary therefrom or with other
12 applicable statutory or decisional law, Defendants deny those allegations. Defendants deny the
13 remaining allegations in Paragraph 29.

14 **MEDICARE PART C RISK-ADJUSTMENT PAYMENTS**

15 30. Paragraph 30 contains no allegations with respect to a particular Defendant or
16 claim, and therefore no response is required. However, to the extent Paragraph 30 purports to
17 summarize and/or describe the provisions of the Medicare program, Defendants state that the
18 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
19 Paragraph 30 vary therefrom or with other applicable statutory or decisional law, Defendants
20 deny those allegations.

21 31. Paragraph 31 contains no allegations with respect to a particular Defendant or
22 claim, and therefore no response is required. However, to the extent Paragraph 31 purports to
23 summarize and/or describe the provisions of the Medicare program, Defendants state that the
24 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
25 Paragraph 31 vary therefrom or with other applicable statutory or decisional law, Defendants
26 deny those allegations.

27 32. Paragraph 32 contains no allegations with respect to a particular Defendant or
28 claim, and therefore no response is required. However, to the extent Paragraph 32 purports to

1 summarize and/or describe the provisions of the Medicare program, Defendants state that the
2 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
3 Paragraph 32 vary therefrom or with other applicable statutory or decisional law, Defendants
4 deny those allegations.

5 33. Paragraph 33 contains no allegations with respect to a particular Defendant or
6 claim, and therefore no response is required. However, to the extent Paragraph 33 purports to
7 summarize and/or describe the provisions of the Medicare program, Defendants state that the
8 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
9 Paragraph 33 vary therefrom or with other applicable statutory or decisional law, Defendants
10 deny those allegations.

11 34. Defendants admit that Sutter and PAMF receive a contractually-determined
12 percentage of CMS payments from MA Organizations with which they contract. To the extent
13 Paragraph 34 purports to summarize and/or describe the provisions of the Medicare program,
14 Defendants state that the Medicare statute and regulations speak for themselves, and to the extent
15 that the allegations in Paragraph 34 vary therefrom or with other applicable statutory or
16 decisional law, Defendants deny those allegations. Defendants deny the remaining allegations in
17 Paragraph 34.

18 35. To the extent Paragraph 35 purports to summarize and/or describe the provisions
19 of the Medicare program, Defendants state that the Medicare statute and regulations speak for
20 themselves, and to the extent that the allegations in Paragraph 35 vary therefrom or with other
21 applicable statutory or decisional law, Defendants deny those allegations. Defendants deny the
22 remaining allegations in Paragraph 35.

23 36. To the extent Paragraph 36 purports to summarize and/or describe the provisions
24 of the Medicare program, Defendants state that the Medicare statute and regulations speak for
25 themselves, and to the extent that the allegations in Paragraph 36 vary therefrom or with other
26 applicable statutory or decisional law, Defendants deny those allegations. Paragraph 36 also
27 states legal conclusions to which no response is required. Defendants deny the remaining
28 allegations in Paragraph 36.

1 37. To the extent Paragraph 37 purports to summarize and/or describe the provisions
2 of the Medicare program, Defendants state that the Medicare statute and regulations speak for
3 themselves, and to the extent that the allegations in Paragraph 37 vary therefrom or with other
4 applicable statutory or decisional law, Defendants deny those allegations. Paragraph 37 also
5 states legal conclusions to which no response is required. Defendants deny the remaining
6 allegations in Paragraph 37.

7 **SUTTER AND PAMF'S KNOWLEDGE AND POLICIES RELATING TO RAF**

8 38. Defendants deny all allegations in Paragraph 38.

9 39. To the extent Paragraph 39 purports to describe a document or documents, such
10 documents speak for themselves and, as such, no response is required. Defendants deny the
11 remaining allegations in Paragraph 39.

12 40. To the extent Paragraph 40 purports to describe a document or documents,
13 including email communications, such documents speak for themselves and, as such, no
14 response is required. Defendants deny the remaining allegations in Paragraph 40.

15 41. To the extent Paragraph 41 purports to describe a document or documents,
16 including email communications, such documents speak for themselves and, as such, no
17 response is required. Defendants deny the remaining allegations in Paragraph 41.

18 42. To the extent Paragraph 42 purports to describe Sutter's written policies and
19 procedures, such documents speak for themselves and, as such, no response is required.
20 Defendants deny the remaining allegations in Paragraph 42.

21 43. To the extent Paragraph 43 purports to describe a document or documents,
22 including email communications, such documents speak for themselves and, as such, no
23 response is required. Defendants deny the remaining allegations in Paragraph 43.

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**SUTTER AND PAMF'S AGGRESSIVE CAMPAIGN TO MAXIMIZE
REIMBURSEMENTS¹**

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3 44. To the extent Paragraph 44 purports to describe a document or documents,
4 including email communications, such documents speak for themselves and, as such, no
5 response is required. Defendants deny the remaining allegations in Paragraph 44.

6 45. To the extent Paragraph 45 purports to describe a document or documents,
7 including email communications, such documents speak for themselves and, as such, no
8 response is required. Defendants deny the remaining allegations in Paragraph 45.

9 46. To the extent Paragraph 46 purports to describe a document or documents,
10 including email communications, such documents speak for themselves and, as such, no
11 response is required. Defendants deny the remaining allegations in Paragraph 46.

12 47. To the extent Paragraph 47 purports to describe a document or documents,
13 including email communications, such documents speak for themselves and, as such, no
14 response is required. Defendants deny the remaining allegations in Paragraph 47.

15 48. Defendants deny all allegations in Paragraph 48.

16 49. To the extent Paragraph 49 purports to describe a document or documents,
17 including email communications, such documents speak for themselves and, as such, no
18 response is required. Defendants deny the remaining allegations in Paragraph 49.

19 50. To the extent Paragraph 50 purports to describe a document or documents,
20 including email communications, such documents speak for themselves and, as such, no
21 response is required. Defendants deny the remaining allegations in Paragraph 50.

22 51. To the extent Paragraph 51 purports to describe a document or documents,
23 including email communications, such documents speak for themselves and, as such, no
24 response is required. Defendants deny the remaining allegations in Paragraph 51.

25 52. Defendants deny all allegations in Paragraph 52.
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28 ¹ Defendants have taken the Complaint's headings verbatim and only repeat them here for
reference. Defendants deny the Government's characterization of each heading contained in the
Complaint.

1 53. To the extent Paragraph 53 purports to describe a document or documents,
2 including email communications, such documents speak for themselves and, as such, no
3 response is required. Defendants deny the remaining allegations in Paragraph 53.

4 54. Defendants deny all allegations in Paragraph 54.

5 55. To the extent Paragraph 55 purports to describe a document or documents,
6 including email communications, such documents speak for themselves and, as such, no
7 response is required. Defendants deny the remaining allegations in Paragraph 55.

8 56. To the extent Paragraph 56 purports to describe a document or documents,
9 including email communications, such documents speak for themselves and, as such, no
10 response is required. Defendants deny the remaining allegations in Paragraph 56.

11 57. To the extent Paragraph 57 purports to describe a document or documents,
12 including email communications, such documents speak for themselves and, as such, no
13 response is required. Defendants deny the remaining allegations in Paragraph 57.

14 58. To the extent Paragraph 58 purports to describe a document or documents,
15 including email communications, such documents speak for themselves and, as such, no
16 response is required. Defendants deny the remaining allegations in Paragraph 58.

17 **RED FLAG – POOR RESULTS IN MA ORGANIZATION AUDITS**

18 59. Defendants deny all allegations in Paragraph 59.

19 60. To the extent Paragraph 60 purports to describe a document or documents, such
20 documents speak for themselves and, as such, no response is required. Defendants deny the
21 remaining allegations in Paragraph 60.

22 61. Defendants deny all allegations in Paragraph 61.

23 62. To the extent Paragraph 62 purports to describe a document or documents,
24 including email communications, such documents speak for themselves and, as such, no
25 response is required. Defendants deny the remaining allegations in Paragraph 62.

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1 **RED FLAG - THE INEFFECTIVE COMPLIANCE AND TRAINING PROGRAMS FOR**
2 **RISK-ADJUSTMENT CODING**

3 63. Defendants deny all allegations in Paragraph 63.

4 64. To the extent Paragraph 64 purports to describe a document or documents,
5 including email communications, such documents speak for themselves and, as such, no
6 response is required. Defendants deny the remaining allegations in Paragraph 64.

7 65. Defendants deny all allegations in Paragraph 65.

8 66. Defendants deny all allegations in Paragraph 66.

9 67. To the extent Paragraph 67 purports to describe a document or documents,
10 including email communications, such documents speak for themselves and, as such, no
11 response is required. Defendants deny the remaining allegations in Paragraph 67.

12 68. Defendants deny all allegations in Paragraph 68.

13 69. To the extent Paragraph 69 purports to describe a document or documents,
14 including email communications, such documents speak for themselves and, as such, no
15 response is required. Defendants deny the remaining allegations in Paragraph 69.

16 70. Defendants deny all allegations in Paragraph 70.

17 **RED FLAG – ORMSBY’S AUDIT RESULTS PROVIDED SUTTER AND PAMF WITH**
18 **ACTUAL NOTICE ABOUT THOUSANDS OF FALSE CLAIMS**

19 71. Defendants deny all allegations in Paragraph 71.

20 72. To the extent Paragraph 72 purports to describe a document or documents,
21 including email communications, such documents speak for themselves and, as such, no
22 response is required. Defendants deny the remaining allegations in Paragraph 72.

23 73. To the extent Paragraph 73 purports to describe a document or documents,
24 including email communications, such documents speak for themselves and, as such, no
25 response is required. Defendants deny the remaining allegations in Paragraph 73.

26 74. To the extent Paragraph 74 purports to describe a document or documents,
27 including email communications, such documents speak for themselves and, as such, no
28 response is required. Defendants deny the remaining allegations in Paragraph 74.

1 75. To the extent Paragraph 75 purports to describe a document or documents,
2 including email communications, such documents speak for themselves and, as such, no
3 response is required. Defendants deny the remaining allegations in Paragraph 75.

4 76. To the extent Paragraph 76 purports to describe a document or documents,
5 including email communications, such documents speak for themselves and, as such, no
6 response is required. Defendants deny the remaining allegations in Paragraph 76.

7 77. To the extent Paragraph 77 purports to describe a document or documents,
8 including email communications, such documents speak for themselves and, as such, no
9 response is required. Defendants deny the remaining allegations in Paragraph 77.

10 78. To the extent Paragraph 78 purports to describe a document or documents,
11 including email communications, such documents speak for themselves and, as such, no
12 response is required. Defendants deny the remaining allegations in Paragraph 78.

13 79. To the extent Paragraph 79 purports to describe a document or documents,
14 including email communications, such documents speak for themselves and, as such, no
15 response is required. Defendants deny the remaining allegations in Paragraph 79.

16 80. To the extent Paragraph 80 purports to describe a document or documents,
17 including email communications, such documents speak for themselves and, as such, no
18 response is required. Defendants deny the remaining allegations in Paragraph 80.

19 81. To the extent Paragraph 81 purports to describe a document or documents,
20 including email communications, such documents speak for themselves and, as such, no
21 response is required. Defendants deny the remaining allegations in Paragraph 81.

22 82. To the extent Paragraph 82 purports to describe a document or documents,
23 including email communications, such documents speak for themselves and, as such, no
24 response is required. Defendants deny the remaining allegations in Paragraph 82.

25 83. Defendants deny all allegations in Paragraph 83.

26 84. To the extent Paragraph 84 purports to describe a document or documents,
27 including email communications, such documents speak for themselves and, as such, no
28 response is required. Defendants deny the remaining allegations in Paragraph 84.

1 85. Defendants deny all allegations in Paragraph 85.

2 86. To the extent Paragraph 86 purports to describe a document or documents,
3 including email communications, such documents speak for themselves and, as such, no
4 response is required. Defendants deny the remaining allegations in Paragraph 86.

5 87. To the extent Paragraph 87 purports to describe a document or documents,
6 including email communications, such documents speak for themselves and, as such, no
7 response is required. Defendants deny the remaining allegations in Paragraph 87.

8 88. Defendants deny all allegations in Paragraph 88.

9 89. To the extent Paragraph 89 purports to describe a document or documents,
10 including email communications, such documents speak for themselves and, as such, no
11 response is required. Defendants deny the remaining allegations in Paragraph 89.

12 90. To the extent Paragraph 90 purports to describe a document or documents,
13 including email communications, such documents speak for themselves and, as such, no
14 response is required. Defendants deny the remaining allegations in Paragraph 90.

15 **SUTTER AND PAMF KNOWINGLY IGNORED RED FLAGS AND ACTUAL NOTICE**
16 **OF FALSE CLAIMS AND THWARTED EFFORTS TO IMPROVE CODING**

17 91. Defendants deny all allegations in Paragraph 91.

18 92. Defendants deny all allegations in Paragraph 92.

19 93. To the extent Paragraph 93 purports to describe a document or documents,
20 including email communications, such documents speak for themselves and, as such, no
21 response is required. Defendants deny the remaining allegations in Paragraph 93.

22 94. To the extent Paragraph 94 purports to describe a document or documents,
23 including email communications, such documents speak for themselves and, as such, no
24 response is required. Defendants deny the remaining allegations in Paragraph 94.

25 95. Defendants deny all allegations in Paragraph 95.

26 96. To the extent Paragraph 96 purports to describe a document or documents,
27 including email communications, such documents speak for themselves and, as such, no
28 response is required. Defendants deny the remaining allegations in Paragraph 96.

1 97. Defendants deny all allegations in Paragraph 97.

2 98. Defendants deny all allegations in Paragraph 98.

3 99. Defendants deny all allegations in Paragraph 99.

4 100. To the extent Paragraph 100 purports to describe a document or documents,
5 including email communications, such documents speak for themselves and, as such, no
6 response is required. Defendants deny the remaining allegations in Paragraph 100.

7 101. To the extent Paragraph 101 purports to describe a document or documents,
8 including email communications, such documents speak for themselves and, as such, no
9 response is required. Defendants deny the remaining allegations in Paragraph 101.

10 102. Defendants deny all allegations in Paragraph 102.

11 103. Defendants deny all allegations in Paragraph 103.

12 104. To the extent Paragraph 104 purports to describe a document or documents,
13 including email communications, such documents speak for themselves and, as such, no
14 response is required. Defendants deny the remaining allegations in Paragraph 104.

15 105. To the extent Paragraph 105 purports to describe a document or documents,
16 including email communications, such documents speak for themselves and, as such, no
17 response is required. Defendants deny the remaining allegations in Paragraph 105.

18 106. To the extent Paragraph 106 purports to describe a document or documents,
19 including email communications, such documents speak for themselves and, as such, no
20 response is required. Defendants deny the remaining allegations in Paragraph 106.

21 107. To the extent Paragraph 107 purports to describe a document or documents,
22 including email communications, such documents speak for themselves and, as such, no
23 response is required. Defendants deny the remaining allegations in Paragraph 107.

24 108. Defendants deny all allegations in Paragraph 108.

25 109. To the extent Paragraph 109 purports to describe a document or documents,
26 including email communications, such documents speak for themselves and, as such, no
27 response is required. Defendants deny the remaining allegations in Paragraph 109.

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1 110. To the extent Paragraph 110 purports to describe a document or documents,
2 including email communications, such documents speak for themselves and, as such, no
3 response is required. Defendants deny the remaining allegations in Paragraph 110.

4 111. To the extent Paragraph 111 purports to describe a document or documents,
5 including email communications, such documents speak for themselves and, as such, no
6 response is required. Defendants deny the remaining allegations in Paragraph 111.

7 112. To the extent Paragraph 112 purports to describe a document or documents,
8 including email communications, such documents speak for themselves and, as such, no
9 response is required. Defendants deny the remaining allegations in Paragraph 112.

10 113. To the extent Paragraph 113 purports to describe a document or documents,
11 including email communications, such documents speak for themselves and, as such, no
12 response is required. Defendants deny the remaining allegations in Paragraph 113.

13 114. To the extent Paragraph 114 purports to describe a document or documents,
14 including email communications, such documents speak for themselves and, as such, no
15 response is required. Defendants deny the remaining allegations in Paragraph 114.

16 115. Defendants deny all allegations in Paragraph 115.

17 116. Defendants deny all allegations in Paragraph 116.

18 117. Defendants deny all allegations in Paragraph 117.

19 118. Defendants deny all allegations in Paragraph 118.

20 119. To the extent Paragraph 119 purports to describe a document or documents,
21 including email communications, such documents speak for themselves and, as such, no
22 response is required. Defendants deny the remaining allegations in Paragraph 119.

23 120. To the extent Paragraph 120 purports to describe a document or documents,
24 including email communications, such documents speak for themselves and, as such, no
25 response is required. Defendants deny the remaining allegations in Paragraph 120.

26 121. Defendants deny all allegations in Paragraph 121.

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1 122. To the extent Paragraph 122 purports to describe a document or documents,
2 including email communications, such documents speak for themselves and, as such, no
3 response is required. Defendants deny the remaining allegations in Paragraph 122.

4 123. To the extent Paragraph 123 purports to describe a document or documents,
5 including email communications, such documents speak for themselves and, as such, no
6 response is required. Defendants deny the remaining allegations in Paragraph 123.

7 124. To the extent Paragraph 124 purports to describe a document or documents,
8 including email communications, such documents speak for themselves and, as such, no
9 response is required. Defendants deny the remaining allegations in Paragraph 124.

10 **ACCURATE DIAGNOSIS CODING'S CRITICAL IMPORTANCE TO CMS**

11 125. Defendants deny all allegations in Paragraph 125.

12 126. To the extent Paragraph 126 purports to summarize and/or describe the provisions
13 of the Medicare program, Defendants state that the Medicare statute and regulations speak for
14 themselves, and to the extent that the allegations in Paragraph 126 vary therefrom or with other
15 applicable statutory or decisional law, Defendants deny those allegations.

16 127. Paragraph 127 contains no allegations with respect to a particular Defendant or
17 claim, and therefore no response is required. However, to the extent Paragraph 127 purports to
18 summarize and/or describe the provisions of the Medicare program, Defendants state that the
19 Medicare statute and regulations speak for themselves, and to the extent that the allegations in
20 Paragraph 127 vary therefrom or with other applicable statutory or decisional law, Defendants
21 deny those allegations.

22 128. To the extent Paragraph 128 purports to describe a document or documents,
23 including email communications, such documents speak for themselves and, as such, no
24 response is required. Defendants deny the remaining allegations in Paragraph 128.

25 129. Paragraph 129 states legal conclusions to which no response is required.
26 Defendants deny the remaining allegations in Paragraph 129.

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1 140. Paragraph 140 states legal conclusions to which no response is required. To the
2 extent Paragraph 140 contains any factual allegations, such allegations are denied.

3 141. Paragraph 141 states legal conclusions to which no response is required. To the
4 extent Paragraph 141 contains any factual allegations, such allegations are denied.

5 **THIRD CLAIM FOR RELIEF**

6 **False Claims Act: Presentation of False or Fraudulent Claims**

7 **31 U.S.C. § 3729 (a)(1)(A)**

8 142. Defendants incorporate their responses to each and every allegation set forth in
9 Paragraphs 1-133 above as if fully stated herein.

10 143. Paragraph 143 states legal conclusions to which no response is required. To the
11 extent Paragraph 143 contains any factual allegations, such allegations are denied.

12 144. Paragraph 144 states legal conclusions to which no response is required. To the
13 extent Paragraph 144 contains any factual allegations, such allegations are denied.

14 145. Paragraph 145 states legal conclusions to which no response is required. To the
15 extent Paragraph 145 contains any factual allegations, such allegations are denied.

16 **FOURTH CLAIM FOR RELIEF**

17 **False Claims Act: Making or Using False Records or Statements**

18 **31 U.S.C. § 3729 (a)(1)(B)**

19 146. Defendants incorporate their responses to each and every allegation set forth in
20 Paragraphs 1-133 above as if fully stated herein.

21 147. Paragraph 147 states legal conclusions to which no response is required. To the
22 extent Paragraph 147 contains any factual allegations, such allegations are denied.

23 148. Paragraph 148 states legal conclusions to which no response is required. To the
24 extent Paragraph 148 contains any factual allegations, such allegations are denied.

25 149. Paragraph 149 states legal conclusions to which no response is required. To the
26 extent Paragraph 149 contains any factual allegations, such allegations are denied.

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1 **FIFTH CLAIM FOR RELIEF**

2 **Payment by Mistake**

3 150. Defendants incorporate their responses to each and every allegation set forth in
4 Paragraphs 1-133 above as if fully stated herein.

5 151. Paragraph 151 states legal conclusions to which no response is required. To the
6 extent Paragraph 151 contains any factual allegations, such allegations are denied.

7 152. Paragraph 152 states legal conclusions to which no response is required. To the
8 extent Paragraph 152 contains any factual allegations, such allegations are denied.

9 **SIXTH CLAIM FOR RELIEF**

10 **Unjust Enrichment**

11 153. Defendants incorporate their responses to each and every allegation set forth in
12 Paragraphs 1-133 above as if fully stated herein.

13 154. Paragraph 154 states legal conclusions to which no response is required. To the
14 extent Paragraph 154 contains any factual allegations, such allegations are denied.

15 155. Paragraph 155 states legal conclusions to which no response is required. To the
16 extent Paragraph 155 contains any factual allegations, such allegations are denied.

17 **PRAYER**

18 All paragraphs in this section contain a prayer for relief to which no response is required.
19 To the extent a response is required, Defendants deny any remaining allegations in the
20 Complaint and deny that the United States is entitled to any relief whatsoever against
21 Defendants.

22 **DEMAND FOR JURY TRIAL**

23 This section contains a prayer for relief to which no response is required.

24 **AFFIRMATIVE DEFENSES**

25 Defendants plead the following affirmative defenses and reserve the right to assert
26 additional affirmative defenses to the extent that such defenses become known as a result of
27 discovery or otherwise:
28

1 1. The United States' claims are barred, in whole or in part, by the statute of
2 limitations, as they incorporate acts that occurred more than six years prior to the
3 commencement of Relator's *qui tam* action.

4 2. The conduct of the United States in continuing to pay Medicare Advantage plans
5 at a previously determined rate as long as the plans' diagnosis coding error rates did not exceed
6 CMS's own error rate, even when CMS knew that diagnosis codes were unsupported, negates the
7 materiality of any alleged misrepresentations by Defendants and thus, the United States and
8 Relators cannot recover under the Complaint against Defendants.

9 3. Defendants are not vicariously liable, in whole or in part, for the acts alleged in
10 the Complaint, including physicians' individual determinations as to whether any given
11 diagnosis code accurately represented the condition of their patients.

12 4. The United States' claims are barred, in whole or in part, by the existence of an
13 express contract that did not establish the requirements with regard to submission of diagnosis
14 codes that the United States alleges were violated by Defendants.

15 5. Plaintiffs' claims are barred because the alleged false certifications were not a
16 condition of payment and the allegedly false implied certifications concern a statute or regulation
17 that does not expressly require compliance as a condition of payment.

18 6. The services and products reimbursed by the United States under Medicare were
19 worth what the government paid, and the United States cannot demonstrate that payments would
20 have been altered by the omission of the codes at issue.

21 7. The United States' claims based on alleged conduct by Defendants are barred, in
22 whole or in part, by the fact that the United States has suffered no actual injury.

23 8. The United States' claims based on alleged conduct by Defendants are barred, in
24 whole or in part, because of the prior public disclosures of the core allegations upon which the
25 Complaint's "false claims" allegations purport to be based and/or because Relator is not an
26 "original source" of the information, as defined in the statutes therein, such that she is not
27 entitled to pursue this action or be awarded any recovery, nor does the Court have
28 jurisdiction.

1 9. The United States' causes of action and allegations in the Complaint are vague,
2 ambiguous and uncertain.

3 10. Damages and claims for which the United States seeks relief in the Complaint, if
4 any, were caused by the acts, errors or omissions or other fault of third parties and/or contributed
5 to and/or other fault of third parties, for whose conduct Defendants were not responsible.

6 11. The United States' alleged damages are speculative, uncertain, or contingent and
7 are not recoverable.

8 12. To the extent any damages are awarded against Defendants, they must be reduced
9 pursuant to 31 U.S.C. § 3729(a)(2).

10 13. The United States' claims are barred, in whole or in part, by the doctrine of
11 estoppel. The United States misrepresented requirements with regard to the submission of
12 diagnosis codes under its Medicare Advantage program, despite knowledge that Defendants
13 understood such requirements differently, thus resulting in Defendants' continued participation
14 in the MA program under false pretenses and ultimately in the United States' allegations of fraud
15 against Defendants in this False Claims Act action.

16 14. The United States ratified, or otherwise consented to, the transactions and
17 occurrences that are the subject of this action, by continuing to pay Medicare Advantage plans at
18 a previously determined rate as long as the plans' diagnosis coding error rates did not exceed
19 CMS's own error rate, even when CMS knew that diagnosis codes were unsupported.

20 15. The United States' claims are barred, in whole or in part, by the doctrines of
21 course of performance, course of dealing, and usage of trade, which govern the meaning of any
22 contractual agreement under which Defendants received payment by the United States.

23 16. The United States' claims are barred, in whole or in part, because any recovery
24 would result in unjust enrichment. The United States alleges that Defendants received an
25 overpayment on the basis of allegedly false diagnosis codes, but does not and cannot allege that
26 these codes impacted the volume of payment Defendants received or that any error in submitting
27 extraneous codes was not countered by codes that Defendants failed to submit. Therefore, any
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1 recovery by the United States would comprise unjust retention of a benefit properly held by
2 Defendants at Defendants' expense.

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By: /s/ Katherine A. Lauer

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