53 N.J.R. 2013(a)

VOLUME 53, ISSUE 23, DECEMBER 6, 2021

RULE ADOPTIONS

Reporter
53 N.J.R. 2013(a)

NJ - New Jersey Register > 2021 > DECEMBER > DECEMBER 6, 2021 > RULE ADOPTIONS > LAW AND PUBLIC SAFETY -- DIVISION OF CONSUMER AFFAIRS

Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF MEDICAL EXAMINERS

Administrative Code Citation

Adopted Amendments: N.J.A.C. 13:35-4A.1 through 4A.12

Adopted New Rule: N.J.A.C. 13:35-4A.19

Adopted Repeal: N.J.A.C. 13:35-4.2

Text

Surgery, Special Procedures, Anesthesia Services Performed in an Office Setting

Proposed: January 4, 2021, at 53 N.J.R. 12(a).

Adopted: October 13, 2021, by the State Board of Medical Examiners, Scott E. Metzger, President.

Filed: November 5, 2021, as R.2021 d.138, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-3.6).

Authority: N.J.S.A. 45:9-2.

Effective Date: December 6, 2021.

Expiration Date: April 3, 2025.

Summary of Public Comments and Agency Responses:

The official comment period ended March 5, 2021. The State Board of Medical Examiners ("Board" or "BME") received comments from:

1. Glenmarie Mathews, MD, MBA, Department of Obstetrics and Gynecology & Reproductive Sciences, Rutgers Robert Wood Johnson Medical School

2. Frank Lopez

3. Heather McCarthy

4. Chimma Nwobi

5. Howard Schwartz

6. John Ilardi

7. Patricia Tomeske

8. Kathleen Lomax, MD

9. Karen Ohland

10. Brian Wolf

11. Alan Gross

12. Carlee Fasano

13. Marag Samuels

14. Sheila Munson

15. Patricia Palermo

16. Dennis Sposato

17. Philip Aronow

18. Faye Feinstein

19. Phoebe Pollinger

20. Fred Roberts

21. Helen Roberts

22. Ariel B.

23. Judy C. Washington, MD, FAAFP

24. Dana Schonberg, MD

25. Kristen Bradi, OB/GYN

26. Rachel Rosenberg, MD

27. Jamie Phifer, MD

28. Dawn Durain, CMN, MPH, FACNM

29. Christina Bartha

30. Margarita Rodriguez

31. Michael J. Donnelly

32. Cathy Howat

33. James Easthope

34. Theresa E. Meagher

35. MaryAnn Preuster

36. Daniel J. Erwin

37. Michael Lindner

38. Michael R. Albert

39. Kathleen Larkin

40. Peter F. Parrinello

41. Barbara Cunningham

42. Barbara O'Connell, RN, CSN

43. Margaret Wysocki

44. Paul K. Anderson

45. Carolina Smith

46. Bill Murphy

47. Stephanie K. Brower

48. Anita Mercanti

49. Rosemarie Colon

50. Jonathan Schwarz

51. Kathleen Diaz-Warwick

52. Mary Menges

53. Anthony Musillo

54. James Marketto

55. Renato Gadenz

56. Ben Nebroski

57. Jacqueline M. Cantu

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59. Hubert Mador

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61. Bill Brewer

62. Jean Antanite

63. Susan Zammit

64. Kristine Cevaso

65. Nora Deemer

66. Diane Potts

67. Katherine Nielson

68. Spookie Maguche

69. Carol Riggs, RN

70. George Tower

71. Lisa Onorato Di Bruno

72. Paul B. Warren

73. Charles Wasilewki

74. Mary Lou Rodimer

75. Linda Rachwalski

76. Denis Mayer

77. Toni Ann Esposito, BSN, CHTP

78. Barbara A. Corio

79. Jo Ann Gerling, IBCLC

80. Maria Franchino

81. Phyllis Martinson

82. Ruth Taberna

83. Carl Lordi

84. Margaret Campbell

85. Anne Cantine

86. Gerald Caporuscio

87. Frank Wimbush

88. Maritza P. Ortiz

89. Bryan A. Ennist

90. Francesca Trousdale

91. James Trousdale

92. Deborah Paulson

93. Rosemarie Manes

94. John Mattei

95. Marianne Kane

96. MaryAnn Carr

97. Jacqueline K. Mazza

98. Arthur Mattei

99. John Peragine

100. Mary Peragine

101. Al Kozikowski

102. Kevin Sallah

103. Twila Metzger

104. Lisa Jenkins

105. Barbara Lacca

106. Lisa Sweetman

107. Linda J. Wiles, LCSW

108. Mary Boxter

109. Dorothy Turse

110. Angela Moll

[page=2014] 111. Mary Wagner

112. James Wilhelmi

113. David Amendola

114. Dr. James E. Brunn

115. Chris Harris

116. Hugh Gilmartin

117. Jackie Von Schmidt

118. Rose Taylor

119. Lea Novak

120. Anna Grinienko

121. Paula Marino

122. Margarita Beltran Sori, PhD

123. William M. McLean

124. Patricia L. Wenzel, MA

125. Claire Burns

126. William Meyer

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128. Cathy Hons

129. Dominick Cuozzo

130. Patricia M. Fesen

131. Amiee Huber

132. Pat Bellen

133. Molly Werosta

134. Mary Moran

135. Diana Lipps, Diana Lipps Tutoring

136. Taffy Spaloss

137. Rev. Judith Valencia

138. Jean Morris

139. Adriel Bastos

140. Anthony Wilkinson

141. Francisco and Kristen Lopez

142. Lianna Schwartz-Orbach

143. Louise Aucott, RN, MS, CNM-Ret.

144. Camille Osborne

145. Karen Ann Kurlander

146. Nina Henry

147. Tom Duffy

148. Jean A. Manigold

149. Dolores Steinberg

150. Laurent Comes

151. Jen Moore Conrow, MFS

152. Carolyn M. Perkins

153. Christine Eisenberg

154. L. Ship

155. Eve E. Slater, MD, FACC

156. National Council of Jewish Women-Bergen County

157. Bill Rosanelli

158. Ann Dillon

159. Gerard V. Burke, MD, Esq.

160. Noa'a Shimoni, MD, MPH

161. Marcella Taggart, RN

162. Donna M. Hayes

163. Barbara K. Eames

164. Lisa A. Clementine

165. Loraine Santarlas

166. Mark Hansinger

167. Elizabeth Egan

168. Laura Anger

169. Miledys Gonzalez, RN

170. Jacqueline (last name unknown), RN

171. Daniela Davidson, B.S. OMS-III, Rowan School of Osteopathic Medicine

172. Marcia Kopytko

173. Tom Huslin

174. Jill Wodnick

175. Andrew Schlafly, Esq.

176. Frederick Boker

177. Isabell Spina

178. Paula G. Zollner, MD, FAAP

179. Arleen A. Hill

180. Helena Beamon

181. Jean Wachter

182. New Jersey State Society of Anesthesiologists (NJSSA)

183. Forum of Nurses in Advanced Practice (FNAP)

184. Brandon McKoy, President; New Jersey Policy Perspective (NJPP)

185. National Council of Jewish Women, Reproductive Rights Committee, Essex County Section

186. Stanton Strong

187. Society for Maternal-Fetal Medicine

188. The National Abortion Federation (NAF)

189. New Jersey Association of Ambulatory Surgery Centers (NJAASC)

190. New Jersey Affiliate of the American College of Nurse Midwives (ACNM)

191. National Organization for Women of New Jersey (NOW-NJ)

192. Physicians for Reproductive Health (PRH)

193. Planned Parenthood Action Fund of NJ (PPAFJ)

194. Melinated Moms

195. American College of Obstetrics and Gynecologists (ACOG NJ)

196. Helen Archontou, MSW, LSW, CEO of YWCA Northern New Jersey

197. New Jersey Abortion Access Fund (NJAAF)

198. America Civil Liberties Union of New Jersey (ACLU-NJ)

199. Guttmacher Institute

200. New Jersey Association of Nurse Anesthetists (NJANA)

201. Cherry Hill Women's Center (CHWC)

202. New Jersey Family Planning League (NJFPL)

203. HiTops

204. National Women's Law Center (NWLC)

205. Nicole Schultz & Carol Loscalzo (Co-chairs of RJTF), Unitarian Universalist Faith Action New Jersey (UUFAN) - Reproductive Justice Task Force

206. Advancing New Standards in Reproductive Health (ANSIRH), University of California-San Francisco

207. Dr. Margaret Lambert-Wooley, MD, OBGYN, Medical Director, Solutions Health & Pregnancy Center, Solutions Board of Medical Directors

208. Dr. Jane Neuman, MD, FACP, Solutions Board of Medical Directors

209. Dr. John M. Taylor, MD, Solutions Board of Medical Directors

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218. Dr. Gerard Ventrella, MD, Solutions Board of Medical Directors

219. Dr. Ziad Abbud, MD, FACC. Solutions Board of Medical Directors

220. American Academy of Medical Ethics (AAME)

221. Rev. Gregory Quinlan on behalf of 11,000 constituents of The Center for Garden State Families

222. Doris Lin, Esq.

223. Kerri Shea

224. Mollie Weisenfeld

225. Dorothy Norris

226. Nadine Maleski

227. Jennifer R. Miller

228. Flor Alto, MD

229. Maria Arvonio, RN

230. May Jen Apiado, MD, MPH, MFM

231. Thaddeus M. Aversa, DO, CMD

[page=2015] 232. Patrica A. Baylog, RN

233. Margaret Brinn, RN

234. Joyce Bulger-Noto, RN

235. John Calabro, MD

236. Karen Cantine, BSN, RN

237. Thomas A. Cavalita, DO, MACOI, FACP

238. Priya Cooper, RDMS

239. Lesly D'Ambola, DO

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241. Gail Dorer, RN, BSPA

242. Alieta Eck, MD, ABIM

243. John Eck, MD

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245. Elenore R. Gaines, MD

246. Michael Giuliano, MD

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248. Ana P. Denisita Gomes DO, CMD, FAAFP

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250. Louis Goyco, MD

251. Molly Jacob, MSN, APN-C, CCRN

252. Selin Jacob RNC, MSN

253. Jisha Jose, RN

254. Maya Joseph, RN

255. Jo Ann Kunweiler-Simon, MSN, NP

256. Priyamol Manoj, MSN

257. Mary Mazzarella, MD; Pediatrician

258. Denise McFadden, MD; Radiologist

259. Vanessa Narcisi, RN

260. Sherine Olickal, RN

261. Charity Onyechi, RN

262. Marybeth Pascale, RN

263. Frederic F. Primich, MD; Surgeon (Retired)

264. Edward R. Prins, MD

265. P. Usha Rosidivito, RN

266. Patricia A, Sayers DNP, RN

267. Bruno Schettini, MD, MBA (Retired)

268. Brian Scully MB, BCh; Professor of Medicine

269. Alan Sori, MD; Surgeon (repetition?)

270. Matthew Y. Suh, MD, MPH; Board-certified Surgeon

271. Bejoy Thomas, LPN

272. Rani Thomas, APN

273. Cynthia Williams

274. Jackie Ramirez

275. Peter Gotlieb

276. B. Hugelmeyer

277. Margarette Alford

278. Lynne Washington

279. Patricia Dingleberry

280. Jeffrey Oppenheim

281. Jesse Reyes

282. Vincent Amari

283. Kevin Halloran

284. Alison Miller

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289. Crystal Lumley

290. Marc Chiarelli

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296. Amanda Harrington

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360. Christine Kwiatek

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365. Jayme Klein

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367. Jaszmene Smith

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418. Veronica Guarraia

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424. Ann Sandritter

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557. Jean Wiant

558. Joann Ramos

559. Alice Logie

560. Gail Gilvey

561. Candace Kautzer

562. C Ortiz

563. Carol Levin

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565. Shirley Finkelstein

566. Barbara Lawrence

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628. Sara Thompson

629. Andrea Watstein

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632. Sherry Taylor

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634. Marcia Kupferberg

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636. Terry Vaccaro

637. Monica Taylor

638. Carol Gay

639. Jean Mauck

640. Barbara Reale

641. Rachel Null

642. Tony Donohoe

643. Carmel Rafalowsky

644. Naz Tiyaloglu

645. Adriana Schwarz

646. Isaiah Rejouis

647. Steven Rudolph

648. Tura Dickert

649. Heidi Dunietz

650. Tracy Foster

651. Juanita Hanley

[page=2018] 652. Veronica Benson-Moore

653. Craig Clark

654. Julie Sacco

655. Sarah Weigele

656. Lisa Murray

657. Stephanie Pistone

658. Wendy Cettina

659. Meryle Melnicoff

660. Thomas Fair

661. Laurie Kraus

662. Iris Sinai

663. Matthew Lipper

664. Chelsea Jankowski

665. Nancy Ginsberg

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667. Glenn Havelock

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669. Wendy Bogle

670. Megan Mauriello

671. Morgan Cormia

672. Denise Lytle

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674. Laura McMullen

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737. Stephanie Schultz

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761. Jennifer Block

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763. Alyssa Sardelli

764. Elizabeth Shpiner

765. Barbara Skokowski

766. Carol Cohen

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768. David Simon

769. Evelyn Kurtzberg

770. Melanie Conlon

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773. Carolyn Lowther

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776. Jason Wiggins

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784. S Barbuto

785. Kathleen Galligan

786. Bharat Adarkar

787. Rosemary Deflorio

788. Nicole Reicher

789. Morgane O'Connell

790. P Scoville

791. Barbara Fleischer

[page=2019] 792. Daryl W. De Boer

793. Ruth Shurkin

794. MaryAnn Sorensen Allacci

795. Katie Brennan

796. Linda K Hardy Hardy

797. Margaret Coveney

798. Matthew Peck

799. Jill Harris

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834. Miriam Ruchman

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836. Susan Walden

837. Noemi Bancroft

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842. Joanne Sanda

843. E. Neal

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845. Mary O'Donnell

846. Harold Lowenfels

847. Barbara King

848. Robin Waddell

849. Joanne Roe

850. Holly Zbierski

851. Cheryl Saccente

852. Dawna Lemaire

853. JJ Mistretta

854. Jerome Zornesky

855. Marcie Case

856. Naomi Ages

857. Anne Ferraioli

858. Denise Kerth

859. Philip Lipardi

860. Lauren Barruzza

861. Georganne D'Angelo

862. G Y

863. Philip Ross

864. Jarod Thomas

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866. Sara Thompson

867. Paula Murphy

868. Carol Short

869. Claire Rupprecht

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876. Rachael Ard

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879. Elise Margulis

880. Diane Chiacchio

881. Ellen Rathbone

882. Danna Seltzer

883. Maria Castro

884. Bonnie MacFarlane

885. Michaeline Snopek

886. George Grant

887. Marjorie Leffler

888. Amy King

889. Emma Impink

890. Karl Johnson

891. Maria Scaglione

892. Thomas Slater

893. Maureen Deam

894. Nicole Plett

895. Barbara Buske

896. Carolyn Niemann

897. Carol Welsch

898. Margaret Walsh

899. Fawn King

900. Louise DiSclafani

901. Cristin Palermo

902. Frank DiDonato

903. Jack Schwartz

904. Matthew Franck

905. Ashley Farreny

906. Dawn Hampton

907. Joseph De Marco

908. Melinda Mucha

909. Barbara Morrison

910. Helen Syen

911. Sarah Seader

912. Jamaul Ramsay

913. Jean Bowman

914. Donna Yavorsky

915. Babette Tenzer

916. Morayo Faleyimu

917. Vicky Skarbek

918. Irwin Lentchner

919. Janice Cooper

920. Joanna Bagatta

921. Judy Gluck

922. Angel Mejias

923. Rosemary Lontka

924. Ann Goldman

925. Hilary May

926. Alison McFarland

927. Janet Lawrence

928. Brian Cochilla

929. Katherine Dennison

930. Christine Novak

931. Laura McMullen

[page=2020] 932. Leigh Adelman

933. Lydia Pfeiffer

934. Susan Blubaugh

935. Marian Zelazny

936. Lydia Haynes

937. Jennifer Chuang

938. Cheryl DiVito

939. Rainer Jurgenstein

940. Nancy Chismar

941. Dipali N

942. Stella Schubert

943. Victoria Martinez

944. Jonathan Tobert

945. Theano Stavrinos

946. Fred Sharp

947. Paulina Subia

948. Colleen Wolfe

949. Gina Rivano

950. Connor Krill

951. Valerie Brett

952. Heather John

953. Maria Casa

954. Dianne Conklyn

955. Nancy Saphier

956. Jae Barboza

957. Barbara Miller

958. Barbara Larson

959. Mary Ciuffitelli

960. Nancy Perlman

961. Deb Ward

962. Debbie Regan

963. Vicki Vranak

964. Scott Mooney

965. Annette Machac

966. Dawn Sudol

967. F Dieckamp

968. Mary Kelman

969. Jeffrey Rattner

970. Kathy Leone

971. Paul Traina

972. Sara Mares

973. Kathleen Fisher

974. Rebecca Pugh

975. Rassoul Faqueri

976. Joyce Kunz

977. Janis Todd

978. Juanita Major

979. Lily Chang

980. Nelson Corcuera

981. Arlene H Beckman

982. Elissa Bennett

983. Lila Rosenthal

984. Kaileen Alston

985. Terry Kaye

986. Beata Teixeira De Mattos

987. Alan Kligerman

988. Steve Gaissert

989. Stuart Weinstock

990. Jacqueline Sornstein

991. David Greenstein

992. John Cantilli

993. John Licwinko

994. Elizabeth Haggerty

995. Andrew Mumford

996. Corie Williams

997. Richard Liroff

998. Dr. Phillip Arnow

999. Deanna Bell

1000. Emily Goldberg

1001. Casey Connor

1002. Dennis Spostato

1003. Charles Neiss

1004. Jennifer Alkiewicz

1005. Louise Passick

1006. Dr. Christine Joseph

1007. Donna Gottlieb

1008. Gale Sasson

1009. Dr. Cheryl Harding

1010. Henry Mitchel

1011. Vanessa Tejada

1012. Martha Learner

1013. Alexandra Raymond

1014. Mary Drody

1015. Emily Patrick

1016. Maureen Keelen

1017. Emily Wirt

1018. Rose Ippolito

1019. Marianne Sperry

1020. Jeffrey Grundy

1021. Gerald Jaffe

1022. Linda Ariel

1023. Carol Adelman

1024. C Slief

1025. Ellen Revesz

1026. Carl and Nancy Gropper

1027. Lauren Bender

1028. Edie Memmott

1029. Natalie Beaumont

1030. Michele Ochsner

1031. Lise Lemieux

1032. Thomas Marlowe

1033. Janet Hubbard

1034. Krista Carboni

1035. Margaret Jelcich

1036. Judith Landau

1037. Anthony Pruzinsky

1038. Richard Angermiller

1039. Genie Barry

1040. William Creeley

1041. Karen S

1042. Barbara Hood

1043. Emily Brudner

1044. Dr. Peter Herzer

1045. Peter Tilgner

1046. Randall Blecher

1047. Jennifer Borghi

1048. Nancy Lem

1049. Sheila Kremer

1050. Janice Hall

1051. Lauren Foss

1052. Kalyani Bhatt

1053. Dr. Paula Danzinger

1054. Bonnie Bayardi

1055. Dr. Gregory Wissink

1056. Robert Szuter

1057. Lorraine Irvine

1058. Carol Greenberg

1059. Peggy O'Brien

1060. John DeGood

1061. Karl Riemann

1062. Dr. Shelden Pisani

1063. Debbie Schepis

1064. Linda Henson

1065. Cynthia Price

1066. Linda Blatnik

1067. Kelly Choi

1068. Thomas Calvanico

1069. Clark Henderson

1070. Jack Tomy

1071. Dr. Philip Waldor

[page=2021] 1072. Mon Mor

1073. Kenneth W Johnson

1074. Bobbi Barbarese

1075. Ashley Wang

1076. Susan Nierenberg

1077. Michelle Boylan

1078. Howard Iwahashi

1079. Daniel Turcich

1080. Mary Irven

1081. Catherine Rymsza

1082. Dr. Erin Zerbo

1083. Kim Kelly

1084. Kaylan Purisima

1085. Jane Paulkovich

1086. Lucinda DeWitt

1087. Cliff Bennette

1088. Dr. Ronald Sverdlove

1089. Arasu Ramalingam

1090. Jeanne Ferrari

1091. Ruth Spae

1092. Vincent Conti

1093. Ellen Pfeffer

1094. Zelda Greenberg

1095. Dr. Duncan Taylor

1096. Helen Blumenthal

1097. Lauren Tuchalski

1098. Brian Moscatello

1099. Naomi Gelfand

1100. Donald Rambo

1101. Elizabeth Tomaselli

1102. Kate Ferraro

1103. Wadyth Zamorano

1104. Debra Cameron

1105. Gautam Gujral

1106. Sue Farro

1107. Marian Campisi

1108. Dr. Sandra Jamieson

1109. Julianna King Williams

1110. William Nierstedt

1111. Moira Goldberg

1112. Paul Palla

1113. Rebecca Rinald

1114. Richard Watson

1115. Elizabeth Tarpy

1116. Carmen Vitale

1117. Christine Koehler

1118. Linda Ringel

1119. Kathy Ferrier

1120. Dr. Deana Stevens

1121. Kameron Raynor

1122. Elaine Golden

1123. Michael Bruncati

1124. David Haas

1125. Michele M. Mlis

1126. Tara Ocello

1127. Timothy McGrail

1128. Monica Hill

1129. Carolina Spiegel

1130. Jenna Weinberg

1131. Amanda Kifferly

1132. Philip Thomas

1133. Denoia Woods

1134. Paula Span

1135. Debra Krevat

1136. Dosier Hammond

1137. Kate Oh

1138. Erica Kaser

1139. Pam Whissel

1140. Jennifer Vilchez

1141. Irene Bremner

1142. Nina P.

1143. Mary Rowson

1144. Perry Cohn

1145. Kathryn Thacker

1146. Dr. Barrie Royce

1147. Lauren Hirschmann

1148. Lauren Giusto

1149. Dr. Rengin Konuk

1150. Alexander Lisse

1151. Sheila Mazar

1152. Jeff M.

1153. Aryadne Valadao

1154. Peri Feldstein

1155. Leeanne Bowen Atkins

1156. Corrado A Rizzi

1157. Jo Ann Macdonnell

1158. Julia Steinberg

1159. Sallie Gordon

1160. Carol Wickersheim

1161. Adam Gross

1162. Dr. Peter Gotlieb

1163. Kiera Mitru

1164. Mike Weiss

1165. Ami Kachalia

1166. Ralph Billick

1167. Hugh Blair

1168. John Keim

1169. Dr. David Rubin

1170. Margaret Ellis

1171. Debbi Pont

1172. Dr. Brian Wright

1173. Cassandra Kalley

1174. Dr. Wayne Goldman

1175. Elaine Silverstein

1176. Monica Sobota

1177. Dr. Martin Carroll

1178. Scott Slavens

1179. Erika B.

1180. Sarah Mercuri

1181. Elizabeth Whitehead

1182. Rosemary Wright

1183. Andrew Kleinberg

1184. William Henderson

1185. Elizabeth Weitzen

1186. Brenda Ramos

1187. Dillon Wu

1188. Charles Rawcliffe

1189. Carol Haag

1190. Valeriya Efimova

1191. Peter Burval

1192. Casey Toutoungi

1193. Elizabeth Klocksin

1194. Frances Recca

1195. Sandra Garcia

1196. Tom Soden

1197. Timothy Carroll

1198. Helene Marley

1199. J. Schwart

1200. Daphne Bloore

1201. Robert Sala

1202. Barbara Andrew

1203. Kathi Cooley

1204. Dr. Norman Grolnick

1205. Lary Campbell

1206. Tonimarie Brusnahan

1207. Carolyn Loudermilk

1208. Michael Luderitz

1209. Dr. Louise Tokarsky-Unda

1210. Patience Armstrong

1211. Natalie Shivers

[page=2022] 1212. Dr. Elaine Barden

1213. Christine Lytle

1214. Shirley Bensetler

1215. Lynn Merle

1216. Michelle Lerner

1217. Linda Hardy

1218. Jacqueline Klein

1219. Kelly Moneyhun Kotch

1220. Jackie Clark

1221. John Lynn

1222. Wayne Hallard

1223. Dr. Heather Van Uxem Lewis

1224. Irene Merlin

1225. Cynthia Gerson

1226. Marjorie Vandervoort

1227. Daniela Nieves

1228. Rolf Figdore

1229. Diane Fisher

1230. Thi Vu

1231. Judith Foys

1232. Karen Jarrett

1233. Paul Meyers

1234. Dr. Myriam Casseus

1235. Nora Hummel

1236. Abby Ow

1237. Jocelyn Block

1238. Rhea Beck

1239. Jo Ann McGreevy

1240. Alejandra Sorto

1241. Alexandra Radbil

1242. Charline Cearfoss

1243. Diane DuBrule

1244. Sue Velez

1245. Noah Mittman

1246. Diane Scarangella

1247. Dr. Carol Harvey

1248. Richard Riggs

1249. Nadina Baskerville-Thomas

1250. Sandy Wilpon

1251. Brent DiBiaso

1252. Stephen Klemash

1253. Harriet Liroff

1254. Diane Swaim

1255. Roberta Van Anda

1256. Howard Weiss

1257. Lily Friedman

1258. Leslie Pessemier

1259. Ellen DeCicco

1260. Dr. Joanne Grossi

1261. Rifka Kreiter

1262. Arthur Rosenberg

1263. Alan Breakstone

1264. Belinda Thomas

1265. Francisco de Vargas

1266. Danielle Soykin

1267. Rita Raftery

1268. Dr. Katrina Low-Beer

1269. Linda Kronemeyer

1270. Wendy Levin

1271. Victor Sytzko

1272. Nancy Loebel

1273. Camille Terracciano

1274. Michael Harrison

1275. Anne Paszamant

1276. Marylin Wechselblatt

1277. Jon Eklund

1278. Paula Maylahn

1279. Barbara Sender

1280. Danielle Goodwin

1281. Carl Oerke, Jr.

1282. Barry Cohen

1283. William Treloar

1284. Pat B

1285. Deborah Collins

1286. Sondra Lampl

1287. Renee Goodwin

1288. Kristen Fitzpatrick

1289. Jim Wooldridge

1290. Kasey March

1291. Eric Gaskill

1292. Jillian Pecoraro

1293. Jane Davidson

1294. Annette Scott, RN, BSN, MSN

1295. Emily Lu

1296. Dr. Robert Koros

1297. Dr. John Womack

1298. Colin Jones

1299. Eric Johnson

1300. Joan Silverman

1301. Carly Cimino

1302. Howard Mead

1303. Diana Mcague

1304. Gilbert Wald

1305. Lisa Friedlander

1306. Philip Lipari

1307. Donna Browne

1308. Dr. William Rogers

1309. Maira Rogers

1310. Carolyn Conover

1311. Carol Cook

1312. Paul Rottmann

1313. James Geraghty

1314. Hannah Blakeman

1315. Wilma Pfeffer

1316. Carolyn Johnson

1317. Gayle McCarthy

1318. David Snope

1319. Rosemary Topar

1320. Katherine Foster

1321. Jessica Hunter

1322. Jamie Merold

1323. Jenise Reedus

1324. Barbara Webster

1325. Paul Thau

1326. Katherine Sastre

1327. Jennifer Donovan

1328. Kim Criscione

1329. Meghan Mertyris

1330. Marli Isaacoff

1331. Elizabeth Breedlove

1332. Erika Martinez

1333. Mary Oliver

1334. Marly Relato

1335. Ramona Hiller-O'Hara

1336. Ashley Few

1337. Dr. Caitlin Killian

1338. Gary Kazin

1339. Dr. Brigitte Mimms

1340. Roberta Blitz

1341. Amy Smith

1342. Faryal Zia

1343. Carolyn Petermann

1344. James Hemm

1345. Mary Cronan

1346. Sheri Abramson

1347. P J September

1348. David Copperman

1349. Mimi Pak

1350. Naomi Weiss

1351. Jeffrey Farenback-Brateman

[page=2023] 1352. Ruth Zowader

1353. Betsy Cousins-Coleman

1354. Tristan Robertson

1355. Jacob Hilton

1356. William Fleming

1357. Judy Fairless

1358. Emily Anna Smith

1359. Paula Ochs

1360. Miriam Rinn

1361. P Naprstek

1362. Abigail Bitterman

1363. Wendy Prychka

1364. Juan Cortez

1365. Michael Meyers-Jouan

1366. Lisa Callender

1367. Andrew Colletto

1368. Jill Arbuckle

1369. Dr. Rachel Fisher

1370. David Blanchard

1371. Sherry Hartman-Apgar

1372. Joann Ramos

1373. Sophia Milone

1374. Sarah Gioe

1375. Karen Davis

1376. Mark Elman

1377. Hernan Sierra

1378. Peter Spool

1379. Jill Melveger

1380. Katherine Schalk-Greene

1381. Sharon Beningo

1382. Patricia Shea

1383. Roe McBurnett

1384. Rhoda Sidney

1385. Ro Green

1386. Astrid Cabrera

1387. Beverly Railsback

1388. Judith Brickman

1389. Karen Curchin

1390. Hope Koturo

1391. Evalyn Gelhaus

1392. Scott Byron

1393. Marissa Braswell

1394. Saul Schreier

1395. Eric Siggins

1396. Dr. Joel Pitt

1397. Stephanie Moncayo

1398. David Rose

1399. Jessica Schwartz

1400. Sam Fine

1401. Joseph Apicella

1402. Amanda Etemad

1403. Russel Miller

1404. Jasmine Anderson

1405. Ronald Weiss

1406. Dr. Anita Mancini

1407. Rebecca Ramirez

1408. Denise Weintraut

1409. John DiPace

1410. Lindsay Holeman

1411. Dr. Evelyn Murphy

1412. Dana Patton

1413. Jennifer Smith

1414. Millie Chen

1415. Philip Wooldridge

1416. Thomas McDermott

1417. Samantha Fantuzzi

1418. Erica Lockhart

1419. A Kasbarian

1420. Carole Botticelli

1421. Elizabeth Reiner

1422. Robert Hearn

1423. Patricia Miller

1424. Dr. Constantine Yapjakis

1425. Eve Gutman

1426. Dinah PoKempner

1427. MichaelAnn Knotts

1428. Patricia Van Horn

1429. Douglas Engle

1430. Dr. Susana Tapia

1431. Abraham Plaut

1432. Dr. Jonathan Greenberg

1433. Elizabeth Adams

1434. Warren Dietz

1435. Emily Hall

1436. Leon Wilson

1437. Linda McKillip

1438. Matthew Goordman

1439. Nano Mardones

1440. Lynn Swanson

1441. Tina Hsu

1442. Elizabeth Nussbaum

1443. Jennifer Manzetti

1444. Francis Murch

1445. Janet Silverman

1446. Fido Margulis

1447. Ruth Kramer

1448. Karen Winner

1449. Christine Clayton-Stroh

1450. Sara Muller

1451. Renee Ducker

1452. Diane Benjamin

1453. Robert MacFarlane

1454. Dr. Lara Freidenfelds

1455. Pamela Williams

1456. Pearl Feder

1457. Timothy Bretschneider

1458. Virginia Rietz

1459. Ellen Dunn

1460. Denise Williams

1461. Marya Parral

1462. Sue Schnaidt

1463. Bernadette Methven

1464. Sherlynn Miller

1465. Jodi Feldman

1466. Sara Borden

1467. Booker Nabors

1468. Casey Haddox

1469. Sandra Weaver

1470. Emily Adcock

1471. Dr. Stephanie Earle

1472. Cade Warrener

1473. Judith Finger

1474. Anita Kranz

1475. Dr. Richard Wedeen

1476. Helen Lindsay

1477. Michelle Mahoney

1478. Paul Netusil

1479. Monica Milano

1480. Donald Masucci

1481. Steve Karmazin

1482. Bettie Reina

1483. Helene Adams

1484. Megan Villone

1485. Maureen Sheehan

1486. Marie Herron

1487. Peter Gilbert

1488. John Schreiber

1489. Kathleen Evans

1490. Amanda Reyes

1491. Terry Cooper

[page=2024] 1492. Susan Clark

1493. Christopher Monroe

1494. Henry M.

1495. Louise McClure

1496. Meliha Bisesar

1497. Alice Meyer

1498. Dr. Leslie Harrison

1499. Ruth Boice

1500. Chris Bozowski

1501. Ellen Froncek

1502. Miriam Eichler

1503. Lisa Polites

1504. Kimberly Mayas

1505. Susan Seuling

1506. Melissa Ramundo

1507. Paul Lucente

1508. Trevanne Foxton

1509. Kendra Poteet

1510. Charles Daly

1511. Halie Hennessey

1512. Erica Lippitz

1513. Faye Timmer

1514. Vera Stillman

1515. Jann Jasper

1516. Bert Morris

1517. Laurel Errington

1518. Steven Boss

1519. Constance Otten

1520. Ralph Notaro

1521. Gregory Clewell

1522. Debra Shuster

1523. Barbara Donovan

1524. Christopher F. Vota

1525. Marissa Grossman

1526. Becky S.

1527. Stephanie Glover

1528. Michelle Edgar

1529. Patricia Chen

1530. Jeanne Waldman

1531. Marian Benedicto

1532. Elisheva Gould

1533. Tracy M

1534. Michael Barnes

1535. Sharon Margulies

1536. Arthur Lisciandro

1537. Robert Travaline

1538. Julie Pauly

1539. Stacie Welsh

1540. Amy Livingston

1541. Linda Maslanko

1542. Ryan Norman

1543. William Slack

1544. Diann Ewan

1545. Katherine Dominguez

1546. Robert Focht

1547. Dr. Max Burger

1548. Concepcion Gracia

1549. Edward R Mayer

1550. Candace O'Malley

1551. Patricia Meko

1552. Francesca Tomaino

1553. Anne Patrone

1554. Lynn Brophy

1555. Sandi Lichtman

1556. Anthony Yee

1557. Claire Abel

1558. Mark Stein

1559. Victoria Mack

1560. Rosemarie Brizak

1561. Claire Whitcomb

1562. Jennie Udell

1563. Alexis Seidel

1564. Ann Babb

1565. Stephanie Yap

1566. Evelyn OBrien

1567. Neil Wise

1568. Melody Schantz

1569. Emma Wagner

1570. Gregory Stankiewicz

1571. Jacqueline Phillips

1572. Noelle Tutunjian

1573. Kate Richman

1574. Elayna Thompson

1575. George Bourlotos

1576. Lara McMullen

1577. Sharon Walker

1578. Alice Ciuffo

1579. Pamela Barroway

1580. Scott Yunker

1581. Michelle Monroe

1582. Princeton Record Lambert

1583. Jae Prowse

1584. Diana and Peter Reed

1585. Marisa Conners

1586. Anne Leyh

1587. Amy Pearlmutter

1588. Mary Previtera

1589. Erin Dennison

1590. Dr. Leslie Bernstein

1591. Kim Luke

1592. Lisa Tracy-Savoie

1593. Anne Hoban

1594. Constance Zarnack

1595. Mary Forrest

1596. Suzanne Apel

1597. Judith Livant

1598. Risa Wallach

1599. Dr. Harvey Cohen

1600. Catherine Brown

1601. Dr. Susan Neigher

1602. Lindsey Avery

1603. Lester Hemphill

1604. Esther Reed

1605. Meredith Kates

1606. Ellen Kovac

1607. Jeanne Gordon

1608. Arina Pabon

1609. Anna Pulgiano

1610. Amy Brooks

1611. Jennie Rothman

1612. Ruthann Fish

1613. Irwin Silverstein

1614. Sharon Davis

1615. Erica Young

1616. Bonnie Monte

1617. Christine Sohn

1618. CJ Griffin

1619. Marnita Robertson

1620. Marc Beebe

1621. James Burnash

1622. Deb Guston

1623. Brianna Khong

1624. Nicole Stewart

1625. Loren Greene

1626. Arianne Sellers

1627. Alexis Karteron

1628. Jessica Desire

1629. Erika Malinoski

1630. Jane Perry

1631. Eve Rametta

[page=2025] 1632. June Bilenky

1633. Ann Mattes

1634. Abby Thurston

1635. Emma Mammano

1636. Kayla Armstrong

1637. Dr. Jan Oosting

1638. Jordan Witt

1639. Andrea Pereda

1640. Georgie Kiely

1641. Rebecca Berkowitz

1642. Carly Nash

1643. Emily Hopkins

1644. Dan Beach

1645. Megan Boyle

1646. Michael Ansell

1647. Kelly Tanis

1648. Brais Castro

1649. Harshini Abbaraju

1650. Yulliet Ruiz

1651. Jenn Fantaccione

1652. Nicole Hengge

1653. Karen Hengge

1654. Kayla Hengge

1655. Justine Fox

1656. Ashley Lockwood

1657. Julianne Vannella

1658. Farah Rahman

1659. Veena Calambur

1660. Dana Irvis

1661. Tracy Dourdis

1662. John O'Connor

1663. Sharon Rothe

1664. Lauren Carozza

1665. Symone Prude

1666. Lauren Carmin

1667. Zachary Cohen

1668. Kirstin Uptegrove

1669. Rebecca Barth

1670. Stacey Gregg

1671. Afsheen Shamsi

1672. Sarah Sturm

1673. CathyWasserman

1674. Maddie Hendl

1675. Danielle Corso

1676. Liza Giuliano

1677. Nicole Gillespy

1678. Marilyn Talmage

1679. Joanne Pawelko

1680. Dr. Bridgid Finn

1681. Ronald Capria

1682. Dr. Kurt Reynertson

1683. William Patton

1684. Joy Simha

1685. Debra Alper

1686. Carol Cain

1687. Emily Muschinske

1688. Olivia Boser

1689. Maria Palmer

1690. Dr. Joan Medina

1691. Elizabeth Herman

1692. Robert Gondelman

1693. Andrea Long

1694. Noah Smith

1695. Elise Brancheau

1696. Regina Smith

1697. Mara Novak

1698. Leslie Bockol

1699. Jami Thall

1700. Rachel Donohue

1701. Amanda Migden

1702. Dr. Amy Green

1703. Regina Branca

1704. Claire Dragon

1705. Liz Reisman

1706. Jennifer Ghannam

1707. James FitzSimmons

1708. Bernadette Jusinski

1709. Linda Vecchione

1710. Ashley Gray

1711. Marilyn Quinn

1712. Dr. Whitney Strub

1713. Alexander Dinell

1714. Matt Dragon

1715. Maria Dorigo

1716. Raquel Mazon Jeffers

1717. Amy Anderson

1718. Rebecca Scheer

1719. Joseph Rogers

1720. Jamie Charles

1721. Chuck Graver

1722. Dr. Al Tino

1723. Blanche Treloar

1724. Nicole Scheller

1725. Skyler Van Valkenburgh

1726. Patricia Dreyfuss, MD, FACOG

1727. Patricia Staley, RN

1728. Joseph Clemente, MD

1729. Connie G. Bareford, PhD, RN, ScPsyA

1730. Arielle Cheifetz, MSN, CNM, WHNP-BC

1731. Kathleen Koutris, RN, BSN

1732. Patricia L. Hunt

1733. Lorraine Santarlas

1734. Mark Hasinger

1735. Frederick F. Fakharzadeh, MD

1736. Cecelia A. Slater, MD

1737. Michele Gilsenan, DO

1738. Maureen Smitley

1739. Francesca Nordin, APN, CPNP-PC, MSN

1740. Donna Cauda, BSN, RN

1741. Krystin Brandi, MD

1742. Yolanda A. Cillo, MD

1743. Richard Pieslak

1744. Kim Clement

1745. Peter Clement

1746. Larry Dillon

1747. Linda Smith

1748. Louis L. Keeler Jr., MD

1749. Mary Eileen Pellecchia, BSN, RN-C

1750. Nancy L. Critchley

1751. Rita M. Benz

1752. Susan Newell

1753. Valentina Kobylinski

1754. Helen Bartek

1755. Dorothy W. Fuchs

1756. Jeryl Turco Maglio, CNHA

1757. Patricia S. Daly, RN, BSN, MSN

1758. James Weidner, MD

1759. Frances Henig

1760. R. Abate

1761. Julia Zheng

1762. Linda Locke

1763. Donna Sullivan

1764. Paula G. Zollner

1765. National Institute for Reproductive Health (NIRH)

1766. New Jersey Health Care Quality Institute (NJHCQI)

1767. New Jersey Right to Life (NJRL)

1768. Advanced Practice Registered Nurse Cluster (co-lead by the National Abortion Federation, Nurses for Sexual and Reproductive Health, and the Reproductive Health Access Process)

1769. New Jersey Catholic Conference (NJCC)

[page=2026] 1770. National Women's Law Center

1. COMMENT: Commenters, including about 850 individuals who submitted to the Board a form comment through Planned Parenthood Action Fund of New Jersey, and about 800 individuals who submitted to the Board a form comment through the American Civil Liberties Union of New Jersey, express support for the rulemaking, stating that the repeal of N.J.A.C. 13:35-4.2 (Rule 4.2) is necessary because the section does not protect a patient's health or safety and restricts access to abortion care in New Jersey.

RESPONSE: The Board thanks the commenters for their support.

2. COMMENT: Commenters who support the rulemaking observe that allowing advanced practice clinicians (specifically advance practice nurses, midwives, and physician assistants, (hereinafter "APCs")) to perform abortion procedures will be particularly helpful to communities facing significant systemic, economic, and logistical barriers to care, and will allow trusted providers to play a role in expanding abortion access.

RESPONSE: The Board thanks the commenters for their support.

3. COMMENT: Commenters who support the rulemaking state their belief that every New Jersey resident should be able to make their own personal medical decisions in consultation with their health care

provider without government interference. About 850 individuals who submitted to the Board a form comment through Planned Parenthood Action Fund of New Jersey, about 800 individuals who submitted to the Board a form comment through the American Civil Liberties Union of New Jersey, and the following organizations included this suggestion in their comments: HiTOPS, Melinated Moms, the National Abortion Federation, Stanton Strong, the New Jersey Affiliate of the American College of Nurse Midwives, National Council of Jewish Women-Essex and Bergen County sections, National Organization for Women of New Jersey, the Unitarian Universalist Faith Action New Jersey, and the National Institute for Reproductive Health.

RESPONSE: The Board thanks the commenters for their support. While governmental requirements are appropriate to protect public health and safety in some circumstances, the Board has determined that the rule as adopted reflects the most appropriate means of protecting public health and safety in the context of abortions.

4. COMMENT: About 850 individuals who submitted to the Board a form comment through Planned Parenthood Action Fund of New Jersey, and about 800 individuals who submitted to the Board a form comment through the American Civil Liberties Union of New Jersey in support of the rulemaking recommend that the Board work in partnership with medical and public health organizations to focus on the experiences of patients and providers who are most directly impacted by these changes to ensure that the rules do not create unintended new barriers and hinder access to care. The following organizations have included these recurring suggestions in their comments: HiTOPS, Melinated Moms, the National Abortion Federation, Stanton Strong, National Organization for Women of New Jersey, New Jersey Family Planning League, Society for Maternal-Fetal Medicine, Guttmacher Institute, National Council of Jewish Women - Essex County section, New Jersey Health Care Quality Institute, and the National Institute for Reproductive Health. RESPONSE: The Board thanks the commenters for their support. With regard to the recommendation, the Board notes that it encourages public participation generally and welcomes feedback from individuals and organizations regarding the implementation of this rule over time. Please visit the Board's website, http://www.njconsumeraffairs.gov/bme, and note meeting dates and times, and the relevant email addresses and other mechanisms for communication with the Board.

5. COMMENT: HiTOPS, which describes itself as a non-profit organization that "represents young people and adults who care for them," expresses its support of the rulemaking. This organization expresses appreciation for efforts to make reproductive health care and abortion more accessible by modernizing the Board's regulations; and expresses its agreement with the Board that abortion is a very safe medical procedure, and that Rule 4.2 is medically unnecessary. This organization also commends the Board for taking steps to remove barriers to access to care at a time when states across the country are moving to make access to abortion more difficult.

RESPONSE: The Board thanks HiTOPS for its support.

6. COMMENT: The National Institute for Reproductive Health (NIRH), which describes itself as an organization that works across the country to increase access to comprehensive reproductive healthcare, including abortion and contraception, expresses support for the rulemaking. In addition to making the recommendations addressed more fully in the Response to Comments 3 and 4, NIRH states that it supports the Board's decision to propose removal of medically unnecessary restrictions on provision of abortions by APCs, and that recent studies indicate abortions are extremely safe and that medically unnecessary regulation of abortion can diminish quality of and access to care.

RESPONSE: The Board thanks NIRH for its support.

7. COMMENT: Melinated Moms, LLC, (Melinated Moms), which describes itself as an organization that represents mothers and women across the Melinated Spectrum and cares about abortion access," expressed its support for the rulemaking and suggests changes summarized and addressed in the Response to Comment 25. This organization expressed appreciation for efforts to make reproductive health care and abortion more accessible by modernizing the Board's regulations. Melinated Moms also agreed with the Board that abortion is a very safe medical procedure, and that Rule 4.2 is medically unnecessary. Melinated Moms supported the expansion of the pool of abortion providers to APCs, observing that this expansion will provide greater access to care for the women it represents and close the marginalization gap they face, allowing these women to thrive, rather than to just survive.

RESPONSE: The Board thanks Melinated Moms for its support.

8. COMMENT: The National Abortion Federation (NAF) expresses its support for the rulemaking and suggests changes summarized and addressed in the Response to Comment 25. NAF stated that it is the leading organization offering accredited continuing medical education to health care professionals in all aspects of abortion care and that NAF facilities adhere to its evidence-based Clinical Policy Guidelines (CPGs), which set the standard for quality abortion care. NAF argues that the pandemic has made clearer the essential need for health care, including abortion care, and the proposed rule will make meeting this need a reality. NAF agreed that expanding the pool of abortion providers to APCs will increase access to abortion care, specifically for those communities who are facing systemic, economic, and logistical barriers and is, therefore, a vital component of providing meaningful access. This organization also commended the Board for taking steps to remove barriers to access to care at a time when states across the country are making access to abortion more difficult.

RESPONSE: The Board thanks NAF for its support.

9. COMMENT: The National Council of Jewish Women - Bergen County Section (NCJW/Bergen) expressed its support for the rulemaking. NCJW/Bergen stated that it represents over 900 members and has a long history of advocating for access to abortion care. This organization expressed its appreciation for efforts to make reproductive health care and abortion more accessible by modernizing the BME's regulations and agreed with the Board that abortion is a very safe medical procedure making Rule 4.2 medically unnecessary. NCJW/Bergen also agreed that expanding the pool of abortion providers to APCs will increase access to abortion care, specifically for those communities who are facing systemic, economic, and logistical barriers, and is, therefore, a vital component of providing meaningful access. Finally, NCJW/Bergen commended the Board for taking steps to remove barriers to access to care at a time when states across the country are making access to abortion more difficult.

RESPONSE: The Board thanks NCJW/Bergen for its support.

10. COMMENT: The New Jersey Affiliate of the American College of Nurse Midwives (ACNM-NJ) expresses its support for the rulemaking. ACNM-NJ states that it represents certified nurse midwives (CNMs) and certified midwives (CMs) in New Jersey. The organization expresses appreciation for efforts to make reproductive health care and abortion more accessible by modernizing BME's regulations and agrees with the Board that abortion is a very safe medical procedure, making Rule 4.2 medically unnecessary. ACNM-NJ expresses particular support for the proposed rule allowing CNMs and CMs to perform abortion procedures and stated that it believes that this will increase access to abortion care,

specifically for those communities who are facing systemic, economic, and logistical barriers, and is, therefore, a vital component of providing meaningful access.

[page=2027] RESPONSE: The Board thanks ACNM-NJ for its support.

11. COMMENT: Stanton Strong, which describes itself as an organization that supports women's reproductive health rights, expressed its support for the rulemaking. The organization expresses appreciation for efforts to make reproductive health care and abortion more accessible by modernizing BME's regulations and voices its agreement with the Board that abortion is a very safe medical procedure making Rule 4.2 medically unnecessary. Stanton Strong also agrees that expanding the pool of abortion providers to APCs will increase access to abortion care, specifically for those communities who are facing systemic, economic, and logistical barriers to care, and is therefore a vital component of providing meaningful access. Finally, the organization commends the Board for taking steps to remove barriers to access to care at a time when states across the country are making access to abortion more difficult.

RESPONSE: The Board thanks Stanton Strong for its support.

12. COMMENT: The Advanced Practice Registered Nurse (APRN) Cluster, co-lead by the National Abortion Federation, Nurses for Sexual Reproductive Health, and Reproductive Health Access Project, expresses its support for the rulemaking. Specifically, this coalition states that it fully supports the finding that current restrictions at Rule 4.2, including the "physician only" provision, are medically unnecessary and serve as barriers to access to abortion care. The APRN Cluster states that advanced practice nurses (APNs) and physician assistants (PAs) have been providing safe and compassionate abortion care to patients since the legalization of abortion and cite to California's Health Pilot Project No. 171, to support their position that APNs can provide care with the same complication and satisfaction rate as physicians. The APRN cluster also listed medical and public health organizations that have concluded that APNs and PAs should be allowed to provide abortion care and that laws that limit this practice are barriers to access. Further, this coalition commended New Jersey in being a national leader in trusting science and expanding access to care, when currently only 11 states allow some or all APCs to provide both medication and aspiration abortion care to their patients.

RESPONSE: The Board thanks APRN for its support.

13. COMMENT: The National Organization for Women of New Jersey, (NOW-NJ), which describes itself as a multi-issue, multi-strategy organization that takes a holistic approach to women's rights, writes in support of the rulemaking. NOW-NJ adds that to ensure equity abortion procedures must be affordable and available to all people. Finally, NOW-NJ commends the Board for taking the steps to modernize its regulations according to the latest scientific evidence.

RESPONSE: The Board thanks NOW-NJ for its support.

14. COMMENT: The New Jersey Family Planning League (NJFPL), which describes itself as an organization that promotes access to patient-centered and evidence-based family planning and reproductive health care services, expresses support for the rulemaking. Specifically, NJFPL notes that the option of abortion is meaningless when it is not accessible or affordable. NJFPL commends the Board's initiative to repeal Rule 4.2 and to allow APCs to perform early aspiration abortions, stating that this would result in greater access to reproductive healthcare, particularly for communities who already face significantly systemic, economic, and logistical barriers to care.

RESPONSE: The Board thanks NJFPL for its support.

15. COMMENT: The Unitarian Universalist Faith Action New Jersey (UUFANJ), which describes itself as an organization that represents the Unitarian Universalist congregations in New Jersey, expresses its support for the rulemaking. UUFANJ states that its support for reproductive justice is rooted in the faith's principle affirming and promoting the inherent worth and dignity of every person. UUFANJ expresses its support for the Board's initiative to modernize its regulations pertaining to abortion, stating that it strongly supports making reproductive health care, including abortion, more accessible in New Jersey, and agrees with the Board that abortion is a very safe medical procedure. UUFANJ also agrees that Rule 4.2 is medically unnecessary and that the expansion of the pool of abortion providers to APCs would effectively increase access to care. Finally, UUFANJ commends the Board in being a national leader when other states are creating barriers to access reproductive health and abortion care.

RESPONSE: The Board thanks UUFANJ for its support.

16. COMMENT: The Society for Maternal-Fetal Medicine (SMFM), expresses its support for the rulemaking. SMFM describes itself as a medical professional society with more than 5,000 physicians, scientists, and pregnancy experts around the world. SMFM states that it supports the clinical practice of maternal-fetal medicine (MFM) by providing education, promoting research, and engaging in advocacy to optimize the health of high-risk pregnant people. SMFM expresses its strong support in making reproductive health services, including abortion, more accessible in New Jersey and nationally. People with high-risk pregnancies, SMFM contends, are more likely to experience medical complications that can lead to increased maternal and perinatal morbidity and mortality and so, in some instances, an abortion may be required to protect the lives or health of such a person. SMFM commends the Board in its initiative to modernize its regulations regarding abortion, in line with scientific evidence and not ideological values. SMFM also agrees with the Board that Rule 4.2 is not medically necessary and creates unnecessary barrier to access, that APCs should be permitted to perform certain abortion procedures, and that abortion is one of the safest medical procedures.

RESPONSE: The Board thanks SMFM for its support.

17. COMMENT: The New Jersey Health Care Quality Institute (NJHCQI), which describes itself as "an independent, nonpartisan advocate that promotes accountability and transparency in health care in New Jersey," expresses its support of the rulemaking and suggests changes summarized and addressed in the Response to Comment 25. NJHCQI states that its mission is to improve the safety, quality, and affordability of health care for everyone and that access to reproductive healthcare, including abortion care, is a priority area for this organization. In support of the rulemaking, NJHCQI commends the Board for taking the steps necessary to modernize its regulations around abortion according to scientific evidence; for proposing to repeal Rule 4.2 because it is medically unnecessary and restricts access to care; for expanding the pool of abortion providers to APCs; and for being a leader in increasing access to abortion at a time when many states across the nation are doing the opposite.

RESPONSE: The Board thanks NJHCQI for its support.

18. COMMENT: The Guttmacher Institute (Guttmacher), which describes itself as an organization that has worked to protect and expand access to reproductive health and rights for more than 50 years, comments in support of the rulemaking. Guttmacher emphasized its strong support for access to abortion care in New Jersey, and commends the Board for: taking the steps to modernize its abortion related

regulations in line with the latest scientific evidence; finding that Rule 4.2 is not medically necessary and restricts access to abortion care; and proposing to expand the pool of abortion providers to APCs, which will result in greater access to care for communities that already face significant systemic, economic, and logistical barriers to such care. Finally, Guttmacher claims that if the rule is adopted, fewer New Jerseyans will have to travel to obtain an abortion and that research has found that distance itself is a barrier to care.

RESPONSE: The Board thanks Guttmacher Institute for its support.

19. COMMENT: Advancing New Standards in Reproductive Health (ANSIRH), which describes itself as a collaborative research program at the Bixby Center for Global Reproductive Health, in the Department of Obstetrics, Gynecology, & Reproductive Sciences at the University of California, San Diego (ESCF), writes in support of the rulemaking. ANSIRH states that it conducts innovative, rigorous multi-disciplinary research on complex issues related to people's sexual and reproductive lives. It notes that its research on abortion found that APCs provide abortion care that is clinically as safe as the care provided by physicians and that outpatient abortion is very safe whether a physician or an APC provides the service, and that patient satisfaction is high when a physician or an APC provides the care. In support of this argument, ANSIRH cites the Health Workforce Pilot Project (HWPP) in California from 2007-2013, that collected data from 20,000 patients and approximately 50 APCs providing aspiration abortion, a study that ultimately informed the passage of AB 154 in 2014.

ANSIRH also notes that its research on the safety of abortion has found that abortions are extremely safe procedures with a complication rate lower than that for miscarriage treatment and wisdom tooth removal; and [page=2028] that there are no benefits from requiring outpatient procedures, including abortions to be performed in an ambulatory surgery center.

RESPONSE: The Board thanks ANSIRH for its support.

20. COMMENT: Physicians for Reproductive Health (PRH), which describes itself as a physician-led national advocacy organization that works to improve access to comprehensive reproductive health care, including abortion care, expresses its support for the rulemaking and suggests changes summarized and addressed in the Response to Comment 25. Specifically, PRH is in support of repealing Rule 4.2 because it states that it is medically unnecessary and harms patients by limiting access to care. PRH cites to the position and finding of the World Health Organization and the American College of Obstetricians and Gynecologists, and several peer-reviewed research publications that conclude that first-trimester abortions performed by APCs are as safe as physicians providing the same service. PRH states that these rule amendments will also increase access for communities who face significant systemic, economic, and logistical barriers to abortion care and notes that APCs are already providing such care in at least 15 states, including the District of Columbia

RESPONSE: The Board thanks PRH for its support.

21. COMMENT: The National Council of Jewish Women (NCJW) Essex County section, an organization that describes itself as representing thousands of members and clients who care about abortion access, writes in support of the rulemaking. The NCJW states that it believes that every New Jerseyan should be able to make their own medical decisions without government interference; expresses appreciation for efforts to make reproductive health care and abortion more accessible by modernizing the BME's regulations; expresses its agreement with the Board that abortion is a very safe medical procedure, and that Rule 4.2 is medically unnecessary. NCJW also agrees that expanding the pool of abortion

providers to APCs will increase access to abortion care, specifically for those communities who are facing systemic, economic, and logistical barriers, and is, therefore, a vital component of providing meaningful access.

NCJW-Essex County section also states that it houses the Linda & Rudy Slucker Center for Women, which provides various career services for women, the majority of whom are low income and represent minority communities. NCJW says that it finds that the reproductive health care needs of these women often take a back seat to the immediate needs of their children and families because of limited resources and that expanding access to reproductive healthcare not readily available across the State would address the unmet needs of this community.

This organization also commends the Board for taking steps to remove barriers to access care at a time when states across the country are moving in the opposite direction in making access to abortion more difficult.

RESPONSE: The Board thanks NCJW-Essex County section for its support.

22. COMMENT: The National Women's Law Center (NWLC), which describes itself as a legal and advocacy organization dedicated to the advancement and protection of women's legal rights and opportunities, writes in support of the rulemaking. NWLC states that it supports efforts to make reproductive health care, including abortion, more accessible in New Jersey. NWLC states that by repealing N.J.A.C. 13:35-4.2, the Board will be implementing the United States Supreme Court's decision in *Whole Woman's Health v. Hellerstedt*. NWLC also supports the Board's efforts to remove restrictions on the performance of certain abortions by APCs.

RESPONSE: The Board thanks NWLC for its support.

23. COMMENT: The New Jersey Abortion Access Fund (NJAAF), which describes itself as an organization that provides financial assistance to those seeking safe, legal abortions, expresses support for the rulemaking. NJAAF states that it supports the Board's efforts to break down financial and logistical barriers to access to care so that individuals need not travel vast distances to obtain, or struggle to pay for, quality abortion care.

RESPONSE: The Board thanks NJAAF for its support.

24. COMMENT: The American Civil Liberties Union Foundation of New Jersey (ACLU-NJ) writes in support of the rulemaking. ACLU-NJ also offers additional changes in furtherance of the BME's intent to remove barriers to abortion care that are not related to safety. See the Response to Comment 25 for more detail. ACLU-NJ notes that the New Jersey constitution clearly protects the right of individuals to control their bodies, including the right to choose abortion.

ACLU-NJ makes the argument that access to abortion is critically necessary for low-income individuals, people of color, and individuals living in rural settings. In support of this argument, it states that 75 percent of abortion patients, nationally, are poor and low-income, and although nearly 40 percent of abortion patients are white, people of color are disproportionately more likely to experience unintended pregnancies and seek abortion care.

RESPONSE: The Board thanks ACLU-NJ for its support.

25. COMMENT: Many commenters who support the rulemaking also offer five suggested changes to it: (1) allow APCs to provide moderate sedation as part of providing abortion care; (2) streamline the new category of abortion services defined in the regulations to simply be named "abortion without anesthesia services"; (3) align the definition of "moderate sedation" with the American Society of Anesthesiologists' definition; (4) ensure that transfer and ambulance agreements are not a barrier for abortion providers; and (5) ensure that both the procedure and anesthesia privileging processes work for abortion providers and do not create additional barriers to access. The following organizations have included these five suggestions in their comments: Physicians for Reproductive Health, Melinated Moms, Health Care Quality Institute, American Civil Liberties Union-New Jersey, and the National Abortion Federation.

RESPONSE: The Board responds to each of these comments below. To the extent that the commenters raise comments beyond the five noted here, those additional comments are addressed in responses to other comments.

1) The Board will not amend the rule to allow APCs to administer moderate sedation, as it remains of the view that specialized anesthesia skill and training is a necessary prerequisite to the administration of "anesthesia services" as defined in the rule to include moderate sedation. The Board has long recognized that those APNs with a specialty in anesthesia (also referred to as CRNAs) do have the requisite skill and training to administer moderate sedation, as well as regional and general anesthesia, in accordance with the requirements of the rule. The Board has not been persuaded by the medical literature reviewed that the skill and training in the curriculum of APCs would support the expansion suggested. At this juncture the Board remains of the view that the public health and safety are safeguarded by requiring that those APNs administering anesthesia have specific training and certification in the delivery of moderate sedation and are working in a team with a physician.

2) The "streamlining" that the commenters have suggested as to the definition of "early aspiration abortion" would remove reference to the first trimester, enabling APCs to perform post-first trimester abortions, so long as anesthesia services are not utilized. The Board will not make the change requested for several reasons. First, as the Board has noted, studies have recognized that later stage abortions are of greater complexity, such that safety concerns dictate physician performance. To have the heightened safety precautions turn exclusively on the use of anesthesia services may present an incentive to practitioners to avoid the use of such anesthesia services when such avoidance would not be consistent with the standard of care or in the best interest of the patient.

3) With regard to the commenters' requested amendment to the definition of "moderate sedation" to more closely align with the definition of the same term that has been adopted by the American Society of Anesthesiologists, see the Response to Comment 27.

4) With regard to transfer and ambulance agreements, the intent of the Board is to modify the rules, so that abortion is treated in a manner similar to all other surgeries and special procedures done in an office setting, so that the requirements for abortion are the same as those for other procedures requiring anesthesia. Treating abortion in a different manner from other health care services arguably would not be as consistent with a fundamental intent of the proposed revisions. The Board will, however, take the issues raised here under review to determine whether these requirements should be modified more broadly, and entertain a new rulemaking in the future, if appropriate. To the extent the commenters have any data relating to the issue, the Board will review it outside of this rulemaking.

[page=2029] 5) The commenters request the Board ensure that the privileging requirement not serve as a barrier for abortion providers. The Board notes that this proposed rule change creates a third, previously unavailable pathway, by recognizing privileges granted by ambulatory surgery centers, in addition to those granted by hospitals and through the Board's own alternative privileging process. The Board does not see the creation of a third pathway as a barrier; in fact, it should make the process of obtaining privileges easier.

26. COMMENT: The New Jersey Section of the American College of Obstetrics and Gynecologists, (ACOG NJ) which has 1,725 members, states that it "advocates for quality health care for women, maintains the highest standards of clinical care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care." ACOG NJ expresses its support for the rulemaking and suggests an amendment to the definition of "early aspiration abortion."

In support of the rulemaking, ACOG NJ states that the proposed regulatory changes will greatly benefit New Jersey patients and clinicians by: (1) removing burdens on physicians by removing medically irrelevant obstacles and unnecessary administrative burdens that have no basis in safety or clinical standards of care; (2) improving patient well-being by removing unnecessary and burdensome government regulations that undermine evidence-based care, which according to a report by the National Academics of Sciences, Engineering, and Medicine (NASEM), are the biggest threat to the quality of abortion care in the United States; and (3) reducing health inequities and systemic racism in health care for individuals who face disproportionate effects of restrictions on abortion access, including adolescents, people of color, those living in rural areas, those with low income, and people who are incarcerated.

ACOG NJ offers the following arguments in support of the rulemaking:

(1) N.J.A.C. 13:35-4.2 is unnecessary for patient health and presents administrative barriers to abortion providers and efficient facility operations; the current credentialing and reporting requirements are burdensome and have no medical, legal, or safety justifications; ACOG NJ along with its colleague organizations have found, after a thorough review of available evidence and guidelines, that abortion regulation is frequently treated differently from other health services by regulations and false concerns are used for specifically targeted abortion regulations; abortion procedures are very safe, with complications being extremely low and that such procedures are not surgeries requiring that they be performed in a hospital or hospital-like facility, such as an ambulatory surgery center.

(2) N.J.A.C. 13:35-4.2, which currently restricts the provision of early abortion care to physicians only, has no medical rationale or benefit because APCs possess the clinical and counseling skills necessary to provide early abortion care; such restrictions block women, especially women who already face the most barriers, from obtaining safe, legal, and accessible abortions; and a substantial, longitudinal body of evidence demonstrates the safety, quality, and patient satisfaction of APC provision of abortion care. ACOG NJ cites multiple studies to support its comments.

ACOG NJ requests the following amendment to the definition of "early aspiration abortion" at N.J.A.C. 13:35-4A.3 to "a procedure that terminates a pregnancy in the first trimester of pregnancy (defined as up to 14 completed weeks as calculated by estimate of gestational age that utilizes last menstrual period, ultrasound, and/or physical examination, as appropriate) utilizing manual or electric suction to empty the

uterus." ACOG NJ argues that defining first trimester pregnancy as "up to 12 completed weeks gestation, as confirmed by the patient, or up to 14 completed weeks as calculated from the last menstrual period and/or by ultrasound" is problematic because it is unclear how a patient would confirm "12 completed weeks of gestation" as the gestational age would still be based on the last menstrual period. Specifically, ACOG NJ recommends amending the definition of "early aspiration abortion" to remove language relating to "12 completed weeks," which ACOG NJ finds confusing and medically inappropriate. ACOG NJ states that the method for determining gestational age should be left to the clinician's professional judgement, adding inclusive but not requisite or prescriptive examples of gestational age determination. ACOG NJ further requests removal of language conditioning the definition of "early aspiration abortion" on the utilization of anesthesia stating "it is worrisome to tie the regulatory definition of a medical procedure to whether another medical treatment or procedure is used."

RESPONSE: The Board thanks ACOG NJ for its support. The Board has considered the recommendation to change the definition of "early aspiration abortion." The Board agrees with ACOG NJ that its proposed language is a clearer statement of the Board's intent that, as applicable, physicians and APCs should have discretion to determine the appropriate method (for example, patient confirmed LMP, physical examination, and/or ultrasound) for gestational dating. The Board also believes that adding explicit reference to the standard of care will further clarify its intent that practitioners be so guided when determining gestational age, such as when the patient is not confident as to the LMP or the stated LMP date is discordant with the physical examination. Additionally, the Board believes the inclusion of "physical examination" is similarly a better encapsulation of the Board's original intent in establishing the methods a practitioner may use to determine gestational age; physical examinations are a fundamental aspect of clinical practice and are consistent with the standard of care in this context, and were, thus, implicitly permissible, at a practitioner's clinical discretion, as a means of determining gestational age under the rule text as originally proposed. Finally, deletion of "does not involve the use of anesthesia" will have no effect on the rule's permitting APCs to perform only early aspiration abortions. Under the proposed rule, "minor procedures" that may be performed by APCs cannot involve "more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intra-operative tranquilization," and a "minor procedure" "specifically excludes all procedures performed using anesthesia services." "Anesthesia services" is defined in the proposed rule as moderate, regional, or general sedation. Therefore, removal of the language "does not involve the use of anesthesia" from the definition of "early aspiration abortion" simplifies the rule language without modifying the substance of the rule as proposed.

27. COMMENT: Planned Parenthood Action Fund of New Jersey (PPAFNJ), writes in support of the rulemaking and recommends amendments. PPAFNJ states that it represents Planned Parenthood of Metropolitan New Jersey and Planned Parenthood of Northern, Central, and Southern New Jersey, which are described as affiliate Planned Parenthood entities, operating 21 health centers, and providing health care and education services to more than 90,000 individuals in New Jersey per year. With the following suggestions and perspective, PPAFNJ notes its concern that abortion may be unnecessarily regulated in a way that hinders access in the following areas:

(1) Definition of abortion: Rather than creating a category for "early aspiration abortion," PPAFNJ, suggests that abortion be treated, instead, like any other medical procedures in New Jersey based on the different levels of anesthesia provided, and so the definition should be changed to "abortion without anesthesia services." PPAFNJ also notes that the category of "special procedures" would continue to apply

to abortions where anesthesia is required, just as with any other type of procedure, and that the proposed definition of "early aspiration abortion" creates new limits on abortion procedures based on procedure type and gestational age, which are not in line with current medical practice.

(2) Privileging requirements: PPAFNJ welcomes the Board's recognition of the validity of ASC privileging. However, PPAFNJ states that this framework provides no path forward for other facilities that do not hold this type of license, and that ASCs are unlikely to begin privileging other providers. PPAFNJ is also concerned by the Board's alternative privileging process, which PPAFNJ believes is inadequate because it is geared toward doctors who have recently completed their training and is not tailored to doctors who are trained later in their careers. PPAFNJ hopes that the BME alternative privileging process will provide another option for doctors who are not directly affiliated with a hospital. PPAFNJ is especially concerned with the retained privileging requirements at N.J.A.C. 13:35-4A.10, which could be a potential restriction of privileging at either a hospital or an ASC for abortions performed with anesthesia. PPAFNJ states that while office-based providers have been subject to this regulation, clinic-based providers under the Department of Health (DOH) jurisdiction have not, and that requiring doctors to go through an additional procedure privileging [page=2030] process, when the current anesthesia privileging process has its challenges, may create unintentional barriers in increasing access to care. Finally, PPAFNJ requests to work with the Board to come up with its own privileging process for anesthesia abortion procedures.

(3) Transfer and ambulance agreements: PPAFNJ is concerned that requiring both transfer and ambulance agreements for any abortion procedure performed with anesthesia would be a new restriction on abortion access since under existing Rule 2.4A, these agreements were not required until 19 weeks LMP or later. In support of this argument, PPAFNJ states that these agreements are difficult to obtain particularly because of the very low rate of complications for these procedures and even for ideological reasons from religiously affiliated hospitals, a barrier not faced by providers of any other medical procedure. PPAFNJ argues that while it understands the goal of treating abortion procedures the same as any other comparable procedures, abortions face unique challenges for the reasons listed above and that an exemption to this requirement should be made for abortion procedures. Alternatively, PPAFNJ suggests that the Board include a non-discrimination provision requiring nearby hospitals and ambulance services to enter into agreements with providers who are required to have transfer and ambulance agreements so that abortion providers are not unfairly disadvantaged by this requirement.

(4) Definition of moderate sedation: PPAFNJ argues that the proposed term "conscious sedation" should be changed to "moderate sedation" to update this term and bring into line with the American Society of Anesthesiologists' (ASA) definition. PPAFNJ also point out that "minimal sedation" is not adequately excluded from the definition of "moderate sedation" and, thus, making the change requested above would eliminate the possibility of the requirements for "moderate sedation" being triggered when minimal sedation is being provided.

(5) APCs' ability to provide anesthesia: PPAFNJ argues that without the ability of APCs to provide anesthesia, except for minor conduction blocks, they would be limited in their ability to provide full-scope abortion care, creating a significant limitation to access to care. PPAFNJ argues that in at least five states--California, Maine, New Hampshire, Oregon, and Vermont--APCs are allowed to provide anesthesia. PPAFNJ then proposes a parallel planning process for how APCs can begin to provide moderate sedation, with the understanding that if this change is included, the State would need to work with APC training programs and hospitals to ensure the appropriate training resources are available and that such training is

included in the anesthesia regulations in the future and a privileging process is available for these clinicians.

(6) Recovery room staffing ratio: PPAFNJ requests that abortion facilities and ASCs that provide abortion care be exempted from the requirement at N.J.A.C. 13:35-4A.7(e) of a greater staffing ratio in the surgical recovery room. The DOH rule, at N.J.A.C. 8:43A-12.15, under which these facilities are regulated, requires at least one RN whenever a patient is in the surgical recovery room with another staff member immediately available, while the Board's regulation would require one RN or PA for the first patient and an additional RN or PA for every additional two patients. PPAFNJ argues that this would be an expensive addition in staffing at facilities that provide abortions, and this requirement is not based on the safety profile of procedural abortions. Therefore, PPAFNJ requests that ambulatory care facilities and ASCs that provide abortions should be exempted from this rule and continue to be regulated under DOH's current requirement, as cited above.

(7) Language regarding medication abortion: PPAFNJ requests that language acknowledging that APCs are allowed to prescribe medication abortion be added at N.J.A.C. 13:35-4A.2 and recommends the following alteration "For purposes of this subchapter, the standards herein have no applicability to the performance of medication abortion, *through prescriptive authority of physicians or advanced practice clinicians.*"

RESPONSE: The Board thanks PPAFNJ for its support. The Board's responses to PPAFNJ follow the above numbered sequence:

(1) With regard to PPAFNJ's request that the definition for "early aspiration abortion" should be replaced with a definition that is not tied to the gestational stage of the pregnancy, but only to whether anesthesia services are used, thus, revising the definition to be "abortion without anesthesia"; The Board does not support the removal of the gestational parameter from the definition. The medical literature reviewed supported the repeal of the "physician only" limitation that had been at N.J.A.C. 13:35-4.2 with respect to first trimester abortions, and that is what guided the expansion to APCs. Moreover, the suggested redefinition would impact the existing protections in the rule and potentially incentivize the performance of procedures without anesthesia services when not in the patient's best interest or consistent with the standard of care. Abortions beyond the first trimester can be performed by physicians in an office setting as special procedures with the attendant safety standards that would apply to other procedures, whether or not anesthesia services accompany the procedure. The Board is of the view that these important safeguards should remain in place at this juncture. With regard to non-substantive changes to the definition of "early aspiration abortion" the Board has determined to make on adoption, see the Response to Comment 26.

(2) With regard to PPAFNJ's concerns about the inability of providers to meet privileging requirements, the Board notes that the rulemaking represents an expansion from prior privileging requirements under Rule 4.2, and that all prior privileging options available at N.J.A.C. 13:35-4A remain available under the rulemaking. As before, non-ASC/hospital affiliated providers can still seek and obtain alternative privileges from the Board. The rulemaking expands the landscape to now allow ASC privileges to also satisfy the privileging requirements. Thus, three privileging scenarios are acceptable to the Board for physicians who require them: hospital privileges; ASC privileges; and/or alternative privileges granted by the Board. APCs are not required to hold privileges.

(3) With regard to transfer and ambulance agreements, the intent of the Board is to modify the rules, so that abortion is treated in a manner similar to all other surgeries and special procedures performed in an office setting, and that the requirements for abortions are, thus, the same as those for other procedures requiring anesthesia. Treating abortion in a different manner from other health care services would arguably undo a fundamental intent of the revisions being proposed. Additionally, the Board does not believe at this time that inclusion of a non-discrimination provision in the rule is necessary, as PPAFNJ suggests. The Board will take the issues raised here under review to determine whether these requirements should be modified and entertain a new rulemaking in the future, if appropriate. To that end, the Board encourages feedback from the public regarding the implementation of this rule and any ongoing or new barriers to care. Regarding the proposed definition of office, the Board notes that upon further consideration regarding the implication of the proposed amendment to the definition of office, it will abandon the proposed change and keep the existing definition of "office." The existing definition of "office" makes clear that licensed ASCs are governed by the New Jersey Department of Health, while the practitioners practicing at those locations remain subject to the jurisdiction of the Board to provide services consistent with the standard of care; therefore, abortions performed in DOH-regulated settings will not also be subject to rules regulating offices.

(4) With regard to the proposed definition of "moderate sedation," the Board agrees that the proposed definition should be changed on adoption to align with the definition used by the American Society of Anesthesiologists (ASA). The Board believes that its definition in the notice of proposal and the ASA's definition are intended to cover identical situations, so to reduce confusion among providers, the Board will modify the proposed definition to more closely track the ASA's. Within the sentence "Cardiovascular function is usually maintained," the Board will insert quotation marks around the words "usually maintained" to indicate that those words are a term of art widely recognized in the medical community, and used in both the American Society of Anesthesiologists definition of "moderate sedation" and the New Jersey Department of Health's definition of "conscious sedation" at N.J.A.C. 8:43A-12.2. Nevertheless, the Board will maintain the final sentence in the proposed definition: "Moderate sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization, such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient," even though this language is not included in ASA's definition, because the Board believes that, given the wide range of procedures that may be undertaken in the office setting, it adds clarity as to which situations involving minimal sedation are excluded from the definition of "moderate sedation."

[page=2031] (5) With regard to PPAFNJ's suggestion that the Board permit APCs to perform moderate sedation, the Board notes that advanced practice nurse anesthetists (APN-A), defined within this rule as certified registered nurse anesthetists (CRNA) are licensed and regulated by the Board of Nursing and are already permitted to administer all three of the defined anesthesia services-moderation sedation, regional anesthesia, and general anesthesia, when appropriately supervised by a physician. To the extent PPAFNJ seeks an expansion of these and other APCs' authority to administer anesthesia, such request is not within the scope of this rulemaking, the purpose of which is to remove unnecessary restrictions on the performance of abortions and bring regulation of abortion care in line with other procedures of comparable complexity and risk. For this reason, the Board will not change that part of the rulemaking.

(6) With regard to PPAFNJ's request that facilities licensed by DOH providing abortion care be exempt from staffing ratio requirements at N.J.A.C. 13:35-4A.7(e), which would be implicated if the proposed definition of "office" is adopted, the Board notes that it has decided not to expand the definition of

"office" to include ASCs. The exclusion of ASCs is made explicit under the existing definition of "office." Therefore, DOH-licensed ambulatory care facilities will continue to be governed, with respect to staffing ratios, solely by the rules promulgated by DOH.

(7) With regard to the request that N.J.A.C. 13:35-4A.2 be amended to clarify that APCs can prescribe medication abortions, the Board notes that the proposed rule language, "For the purposes of this subchapter, the established standards shall not be applicable to the performance of medication abortions, whether as a result of prescriptions issued by physicians or advanced practice clinicians," makes clear that nothing in the rule prohibits APCs from prescribing medication abortions to the full extent of their scope of practice. However, the Board agrees with the commenter that reference to "the standards in this chapter" will more clearly reflect the Board's intent than the proposed wording "the established standards." Therefore, the Board will make this modification to the language of the rule upon adoption.

28. COMMENT: Cherry Hill Women's Center (CHWC), that describes itself as an ambulatory service provider and a first and second trimester abortion care provider for over 40 years, writes in support of the rulemaking. CHWC writes that it commends the BME's efforts to make abortion care more accessible by updating its regulations, in accordance with current clinical practice and scientific evidence.

CHWC writes that as an abortion care provider to thousands of women each year, it knows first-hand that access to abortion care is curtailed by the restrictions at Rule 4.2; that allowing APCs to perform first-trimester abortions will provide greater access to communities facing significant systemic, economic, and logistical barriers to healthcare.

CHWC also proposes the following amendments to the rulemaking: (1) Allowing APCs to provide moderate sedation during abortion procedures as a means to remove barriers to APCs acting within their full scope of practice, which would serve the same goal of increasing access to high quality care. CHWC states that this amendment would be in line with current practice and research. (2) Aligning the standard definition of moderate sedation with the American Society of Anesthesiologists' definition. (3) Amending the term "early aspiration abortion" to "abortion without anesthesia services" and defining it as "a procedure that terminates a pregnancy that does not involve the use of anesthetic services, as defined herein." In support of this amendment CHWC observes that an aspiration is a type of abortion procedure that is whole and separate to the procedure itself. (4) Removing, existing N.J.A.C. 13:35-4A.7(e)5, which requires a 2:1 ratio of patients to qualified registered professionals in the recovery area, in an office setting. CHWC argues, that as an ASC, it is familiar with post-procedure room staffing requirements and that this requirement for an office setting, is higher than the current staffing level requirements under the ASC regulations and that it is clinically unnecessary, as well as cost-prohibitive and will add another barrier to access. CHWC requests that facilities that provide abortion care, therefore, continue to be regulated under the Department of Health's rules for post-anesthesia care.

RESPONSE: The Board thanks CHWC for its support. With regard to CHWC's suggested amendments, please see the Response to Comment 27.

29. COMMENT: The New Jersey Association of Nurse Anesthetists (NJANA) writes to advocate for advanced practice nurse anesthetists' (APN-A)/certified registered nurse anesthetists' (CRNAs) ability to provide anesthesia as required in abortion procedures in an office setting. NJANA states that all its members have sufficient education, training, and malpractice insurance to provide these services. As to education, NJANA states that three decades of peer reviewed evidence shows that APN-As have enough

education to provide this level of anesthesia, which is also consistent with Robert Wood Johnson-Institute of Medicine's 2014 recommendation for the future of the nursing workforce in New Jersey. NJANA notes that all APN-As have a master's degree and as of 2021 are required to have a doctorate degree and that all its New Jersey members are nationally board certified to administer these types of anesthetics. It points out that neighboring states New York, Pennsylvania, and Delaware allow APN-As to provide these types of anesthetics. It also states that APN-As are competent to handle emergency circumstances arising out of any complications from anesthesia, as has been demonstrated during their critical care management of patients in COVID ICUs throughout the State. Finally, it states that APN-As have malpractice insurance that is equal to that of physicians who provide the same services.

RESPONSE: APN-As/CRNAs are licensed and regulated by the Board of Nursing and not this Board. Therefore, this matter is not within the scope of this rulemaking.

30. COMMENT: The Forum of Nurses in Advanced Practice (FNAP) of the New Jersey State Nurses Association and another commenter express their support for the Board's inclusion of APN in the definition of APC and appreciate the intent of the Board to allow APNs to perform early aspiration abortions and other minor procedures within their scope of practice. FNAP also highlights the following concerns and suggested amendments to the rulemaking: (1) Because APNs are licensed and regulated by the New Jersey Board of Nursing (BON) and not the Board, the BON should be recognized at N.J.A.C. 13:35-4A.3 as the body with that authority. (2) Amending the language at N.J.A.C. 13:35-4A.6(c)1 to read (addition in bold) "The practitioner shall appropriately assess, review a referring physician's or advanced practice clinician's assessment of, the physical condition of the patient..." so that APNs can seamlessly refer for surgery. Relatedly, commenters state that while APNs are required pursuant to N.J.A.C. 13:37-6.3 to have a Joint Protocol with a collaborating physician, this requirement is for prescribing medication only, and that under N.J.S.A. 45:11-49.a(3) performance of minor procedures is considered to be an independent function of an APN and does not require an individual collaborating agreement or Joint Protocol. (3) FNAP states that the term "CRNA" has been retired and proposes that it be replaced with the correct term "APNs-anesthesia" within the proposed rule amendments. (4) FNAP requests that the amended rulemakings reflect that APNs-anesthesia are licensed and regulated by, and must meet the requirements for certification, by the BON. (5) FNAP opposes the proposed requirement at amended N.J.A.C. 13:35-4A.7 that an APN-anesthesia practice under direct supervision of a physician. FNAP states that it is committed to achieving Full Practice Authority for all New Jersey APNs without the encumbrance of collaborative or supervisory restrictions, which, according to the Institute of Medicine, do not improve patient health or safety, but rather restrict patient access to care and increase cost of care. Finally, (6) FNAP expresses its concern that APNs in New Jersey were not notified of the rulemaking by the Board, BON, or DCA, when this rulemaking directly impacts the practice of APNs.

RESPONSE: The Board notes that the definition of APC at proposed N.J.A.C. 13:35-4A.3 acknowledges the licensing authority of BON for APNs by citing to the authorizing statute, N.J.S.A. 45:11-45; as such, the Board believes that it is unnecessary to change the rule to reflect that APNs-anesthesia are licensed and regulated by the BON. With regard to FNAP's proposed amendment at N.J.A.C. 13:35-4A.6(c)1, the Board agrees that the text should be changed to include assessments of APCs. With regard to substituting the term "CRNA" with "APN-anesthesia," the Board will not make the requested change, at this time, because the Board of Nursing's rules continue to use the term CRNA and the definition within this proposed rule makes it clear that CRNAs are APN-anesthesia. The Board may, however, address this change in a future, separate rulemaking, if it deems such appropriate. Finally, the Board notes that

[page=2032] APNs, like physicians and other advanced practice clinicians who may be impacted by this rulemaking, were notified of the rulemaking by publication of the notice of proposal in the New Jersey Register, publication of a press release regarding the notice of proposal, and posting of the text of the notice of proposal on the Division's rulemakings webpage (http://www.njconsumeraffairs.gov/Proposals/Pages/bme-01042021-proposal.aspx), and that on January 6, 2021, the Division sent notice of the rulemaking to its list of interested parties through electronic mail.

31. COMMENT: The New Jersey State Society of Anesthesiologists (NJSSA) supports the repeal of the "physician only" rule and allowing APCs to perform early aspiration abortions "to the extent such APCs are properly educated and trained in performing the procedures and handling complications." It attributes the low rate of complications to the fact that they are being performed by "well-trained practitioners." NJSSA opposes certain other aspects of the rule and seeks amendments.

1) It does not support the repeal of those provisions of Rule 4.2 that restricts performance of post-first trimester abortion procedures to hospitals or ASCs.

2) NJSSA asks the Board to revamp its definition of "moderate sedation" to conform to the American Society of Anesthesiologists' (ASA) definition.

3) NJSSA seeks the addition of specific regulatory citations when referencing the collaborating agreements between APCs and physicians.

4) It has requested that the Board engraft upon the provision establishing who can administer moderate sedation a reference to the ASA Guidelines with respect to privileging of non-anesthesia personnel through incorporation by reference in the rule.

5) NJSSA maintains that the provision allowing physicians to authorize APCs to perform minor procedures and administer topical or local anesthesia, minor conduction blocks, pain management or pain medication if these services are "within their scopes of practice and consistent with their individual collaborating agreements" is too vague with regard to the scopes of practice for each category of APC. It calls upon the BME to specifically address scopes of practice, training, and education of midwives and physician assistants, and for the Board of Nursing to do the same for APNs. It further suggests that APNs be "excluded from N.J.A.C. 13:35-4A.19" until the Board of Nursing amends its regulation.

6) Because midwives previously had not been authorized to administer minor conduction blocks, NJSSA states that the experience should be spelled out in the midwifery rules.

7) NJSSA objects to the amendment that would allow reliance on ASC privileging (in addition to hospital and Board privileging) for physicians to utilize retrobulbar blocks, expressing the concern that ASC privileging "is not as consistently exhaustive as hospital privileging."

RESPONSE: The Board thanks the NJSSA for its support for the recognition that APCs should be authorized to perform first trimester abortion with training and experience.

1) Regarding NJSSA's objection to allowing post-first trimester procedures outside of a hospital or ASC, as has been noted in the response to other comments, the Board, in recognition of research and conclusions from a number of studies, determines that there is evidence to support the decision to allow minor procedures, as well as certain special procedures in offices, without the need to require that they be performed in a hospital or ambulatory surgery center. It also notes that at present there are a number of

registered surgical practices that have not yet transitioned to become licensed ambulatory surgery centers that should remain subject to the heightened safety standards at N.J.A.C. 13:35-4A, when surgery or special procedures are performed until they are licensed as ambulatory surgery centers.

2) With regard to the suggestion that the definition of "moderate sedation" be modified, see the Response to Comment 27.

3) In relation to the specific request that the Board identify the regulatory citations for the collaborating agreements for APNs, PAs, and nurse midwives, the definition at N.J.A.C. 13:45-4A.3 makes clear the specific documents to which the term is referring. In the Board's view there is no need to include the specific regulatory references.

4) With regard to the suggestion to amend N.J.A.C. 13:35-4A.10(a) to include language regarding compliance with ASA guidelines and incorporation by reference of those guidelines in the rule, NJSSA has not indicated why doing so would be a necessary or beneficial component of the Board's regulation and the Board believes that existing rules already provide adequate guidance on privileging. Nonetheless, the guidelines adopted by professional associations may provide the Board with context if the Board is called upon to review the standard of care in individual circumstances.

5) NJSSA notes an ongoing need for the Board of Nursing and committees of the Board of Medical Examiners to weigh in on the issue of the scope of practice of their licensees and to identify any training and experience standards that they deem prerequisites to expanded practice. In the coming months the Board expects these issues to be resolved by the relevant subcommittees of this Board and welcomes the opportunity to collaborate with the Board of Nursing.

6) With regard to the suggestion that N.J.A.C. 13:35-4A.11(a)3 be amended to include with specificity the training and experience required of all APCs, including certified midwives, before they may provide minor conduction blocks, the Board notes that the Board of Nursing, Midwifery Liaison Committee, and Physician Assistant Advisory Committee are the regulatory bodies that are best suited to consider whether such requirements should be imposed and to initiate those rulemakings if they are deemed necessary.

7) NJSSA's comment with respect to the rule's addition of a pathway to privileging through ASC privileges appears focused on retrobulbar blocks. In fact, the amendments provide that pathway for those seeking to perform surgical and anesthesia services. Upon review of the rules governing ASC credentialing at N.J.A.C. 8:43A, the Board determined that such rules provide a structure for making determinations with regard to training and experience that the Board concluded was sufficiently comparable to that required in a hospital or through its own alternative privileging process to support the recognition of the additional pathway, thus reducing what might have been perceived to be barriers to care. As registered surgical practices are shifted over to licensed ambulatory surgical centers under the DOH licensing structure, the regulated community will be afforded greater flexibility.

32. COMMENT: The New Jersey Association of Ambulatory Surgery Centers (NJAASC) writes in general opposition to the rulemaking. NJAASC believes that, to the extent access to abortion is a problem in New Jersey, all abortion services should be provided with necessary and rigorous safety measures for all patients. Because of this concern, NJAASC does not support the repeal of Rule 4.2 with regard to facility and provider restrictions. NJAASC further states that the low rate of serious complications, as noted in the notice of proposal, has been due to the fact that a vast majority of these procedures have been performed by well-trained practitioners in hospitals or ambulatory surgery centers (ASCs).

Specifically, NJAASC expresses the following concerns about the rulemaking:

(1) NJAASC believes that the proposed definition of "office" creates a conflict between the Department of Health regulations and Board regulations. In support of this contention, NJAASC states that pursuant to N.J.A.C. 13:35-4A.3, the definition of "office" includes "registered surgical practices" while N.J.S.A. 26:2H-12 and N.J.A.C. 8.43A no longer recognize "registered surgical practices" and require all "surgical practices" to be licensed ambulatory care facilities providing surgical services. This conflict, NJAASC believes will leave the health care community without certainty as to where to lawfully perform abortions.

(2) NJAASC takes issue with renaming "minor surgery" as "minor procedure" at N.J.A.C. 13:35-4A.3 and including early aspiration abortion under this new term. It believes that early aspiration abortions should be performed in either ASCs or hospitals and that these procedures require Subchapter 4A's heightened regulatory requirements, namely, practitioner privileging, patient selection, emergency transfer procedures, patient recovery, patient discharge, and equipment requirements.

(3) NJAASC is not in agreement with including abortion procedures other than early aspiration abortions under the definition of "special procedures" at N.J.A.C. 13:35-4A.3, and allowing these post-first trimester abortions to be performed in offices. It believes that post-first trimester abortions have a higher level of complexity and complications which require these abortions to be performed in ASCs or hospitals. [page=2033] NJAASC also states that the proposed definition of "special procedures" in the rulemaking is not in line with the definition of "special procedures" at DOH's N.J.A.C. 8:43A-12.2, governing ASCs.

RESPONSE: With regard to NJAASC's concern about expanding the group of individuals who may perform early aspiration abortions and about the performance of early aspiration abortions in offices, please see the Response to Comments 36 and 40.

(1) The Board agrees that the proposed definition of the term "office" may lead to confusion among practitioners as to the rules that apply in different settings where abortions may be performed. Therefore, the Board has determined to not adopt the proposed amendments to the definition of "office." The Board believes that the existing definition of "office" provides sufficient clarity to the regulated community as to the Board's intent with regard to the settings at N.J.A.C. 13:35-4A, namely, that ASCs are to comply with physical plant, equipment, and staffing rules promulgated by the Department of Health. The Board further believes that its determination not to adopt the proposed amendments to the definition of "office" will reduce the burden on the regulated community as compared to strict application of the originally proposed rule text.

(2) With regard to definitions of "special procedure," in DOH and Board rules: the Board recognizes that its proposed definition of "special procedure" varies somewhat from DOH's definition of "special procedure" at N.J.A.C. 8:43A-12.2. However, the Board believes that the definitions can coexist. The Board has determined to clarify, in this notice of adoption, that ambulatory surgery centers are excluded from the adopted definition of "office." This amendment makes clear that the Board's rules will apply in offices, while DOH rules will apply in ASCs. For this reason, variation between the two definitions is unlikely to cause conflict because only one definition will apply in any setting.

33. COMMENT: New Jersey Right to Life (NJRL), writes in opposition to the rulemaking. Specifically, NJRL argues that sweeping changes to long-standing policies and procedures, such as this, should be made by the Legislature, not a board appointed by the Governor. NJRL also argues that the Board's

reliance upon the California study, "Safety of Aspiration Abortions Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver" is faulty, because the study found that abortions performed by non-physicians are twice as likely to go wrong as licensed physicians; that according to the study, 30 percent of the women from the 11,487 surgical aspiration abortions completed did not participate in a follow up; and that women were 2.7 times more likely to suffer an incomplete abortion with a non-physician than a licensed physician; and that complications from non-physician abortion providers were "statistically significant." NJRL states that incomplete abortions, if untreated can result in hemorrhaging, infection, or death. Finally, NJRL states that the study is not objective because it was funded by "wealthy donors who are well-known backers of abortion" and that many of the Board's members stand to benefit financially by these proposed changes. NJRL urges the Board not to take actions based on election-year politics.

RESPONSE: The study to which the commenter refers, "Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver," is a prospective, observational cohort study, the results of which were peer-reviewed and published in *The American Journal of Public Health.* The study evaluated 11,487 aspiration abortions to assess "whether the effect of a new treatment [the provision of aspiration abortion by NPs, CNMs and PAs] is not worse than that of an active control [provision of aspiration abortion by physicians] by more than a specified clinically acceptable margin." The study concluded that "the estimated 95% CIs [Confidence Interval] for risk differences in unadjusted, adjusted, and propensity score--- matched analyses all fell well within the predetermined margin of non-inferiority, and therefore complication rates from aspiration abortions performed by recently trained NPs, CNMs, and PAs were statistically no worse than those from those performed by the more experienced physician group." The article further noted that both provider groups (advance practice clinicians and physicians) "had extremely low numbers of complications, less than 2% overall--well below published rates--and only six complications out of 11,487 procedures required hospital-based care." Regarding funding, the foundations providing grant support for the research are noted in the acknowledgments section, as is standard practice. In addition, the "human subject protection" section notes that the "Study protocol and procedures received institutional review board approvals from the University of California, San Francisco; Ethical and Independent Review Services; and Kaiser Permanente of Northern California." With regard to the commenter questioning the Board's authority to make "sweeping changes to long standing policies and procedures," the Board notes that the rules proposed to be repealed and amended (that is Rule 4.2 and N.J.A.C. 13:35-4A) were promulgated and amended through the years by the Board, pursuant to its statutorily-granted rulemaking authority. Absent a statute to the contrary, the Board has the full authority to propose, repeal, and amend its own rules. Thus, this rulemaking is within the Board's purview.

The Board also notes that abortion is legal medical care, access to which is Constitutionally protected. The Board is unaware of any indication that Board members will benefit financially in any way from the Board's rulemaking. With regard to the allegation that the study referenced by the commenters is biased, please see the Response to Comments 34 and 36.

34. COMMENT: Commenters argue that all research, reports, and studies relied upon by the Board in support of the rulemaking are biased because these studies were funded by wealthy, pro-choice supporters, and, therefore, are unreliable.

RESPONSE: The research, reports, and studies relied upon for this rulemaking are peer-reviewed, non-partisan, evidence-based, and have been published by government agencies and by organizations,

associations, and medical journals widely known in the healthcare community to be reputable. For instance, the research paper, "Association of Facility Type with procedural-related Morbidities and Adverse Events among Patients Undergoing Induced Abortions" published in JAMA Network Open, an international peer-reviewed general medical journal, used publicly available data and was peer reviewed for integrity of analysis and accuracy of the data analyzed. For more information on JAMA Network Open's editorial and review process, see: http://jamanetwork.com/journals/jamanetworkopen/pages/instructions-for-authors#SecEditorialandPeerReview. Further, the comprehensive opinion statement on "Abortion Training and Education" (November 2014, *Reaffirmed* 2017), and the position statement on the "Definition of 'Procedures' Related to Obstetrics and Gynecology" (January 2018) of the American College of Obstetrics and Gynecologists (ACOG) is supported by credible research and is affirmed by physicians who specialize in and have first-hand knowledge of abortion care. A brief background of the other institutions, organizations and medical journals compiling the relied-upon research and statistics on abortion care is as follows: (1) The National Academies of Science, Engineering, and Medicine (NASEM) is a private, non-profit, organization created by an Act of Congress in 1863 that provides objective analysis to inform evidence-based policy. The consensus study report, "The Safety and Quality of Abortion Care in the United States" (2018) (NASEM report) published by NASEM's Committee on Reproductive Health Services (NASEM's committee), was peer reviewed by industry experts in accordance with NASEM's guidelines to ensure that the report was accurate and effective. For more information on NASEM's guidelines for review of reports, http://www.nationalacademies.org/about/institutional-policies-and-procedures/guidelines-for-the-review-of-reports; (2) The Centers for Disease Control and Prevention (CDC) is an agency within the executive branch of the Federal government and is charged with protecting the nation's health security. The CDC obtained, and relied upon, abortion related statistics and data from 48 out of 52 regional central health agencies throughout the country to produce its trend analysis of the number and characteristics of women obtaining legal induced abortions; (3) The American Public Health Association (APHA) is a Washington, D.C.-based professional organization for public health professionals in the United States with approximately 25,000 members. APHA's policy statement "Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants" (Nov. 1, 2011) supports the provision of abortion care by nurse practitioners, nurse-midwives, and physician's assistants, with appropriate education and training. This policy statement, similar to other resources the Board has relied upon, reflect the latest available scientific research, and has been vetted to make sure it is accurate and evidence-based, consistent with the development process of APHA's [page=2034] policy statements. See http://publichealthnewswire.org/?p=how-apha-policy-statements-are-developed; (4) Advancing New Standards in Reproductive Health (ANSIRH) is a collaborative research group at the University of California, San Francisco (UCSF)'s Bixby Center for Global Reproductive Health, which conducts research on complex issues related to people's sexual and reproductive lives. ANSIRH's research paper, "Safety of abortion in the United States," finding that abortion was an "extremely" safe procedure, analyzed data for approximately 55,000 abortions and all health care for up to six weeks after the abortion at any clinical site, including emergency rooms and hospitals, in California in 2010; (5) The American Journal of Public Health (AJPH) is the official journal of the American Public Health Association, a hundred year old organization with millions of subscribers, which publishes original work in research, research methods, and program evaluations in the public health field. See: http://ajph.aphapublications.org/page/ajph/about.html. The research report published in AJPH and relied upon by the Board, "Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse

Midwives, and Physicians Assistants under a California Legal Waiver," is the largest and leading study in patient safety data in California. This report found no clinically significant difference in aspiration abortion complication rates between APCs and physicians after analyzing 11,487 aspiration abortions performed by APCs. The study report was peer reviewed, in accordance with the standards of AJPH for acceptance and publication. AJPH's peer review process consists of review by three reviewers and additional assessment by the responsible associate editor, deputy director, and editor-in-chief, a process that takes approximately three months. Peer reviewers are often authors who have expertise in and published work in the related topic. For more information on the publication process including peer reviewers, please see: http://ajph.aphapublications.org/page/authors.html.

35. COMMENT: Solutions Health and Pregnancy Center's (SHPC) Medical Board of Directors (MBOD) writes in opposition to the rulemaking. The MBOD describes SHPC as a non-profit organization that operates a small DOH-licensed ambulatory medical clinic that provides pregnancy testing, ultrasound, options counselling, STD testing, parenting education, material support, and abortion alternative information, but not abortions. SHPC notes in its comment that, "Along with the undersigned, we at Solutions unabashedly respect and seek to protect all human life as a precious gift of God." The SHPC MBOD, consisting of individual physicians experienced in various specialties including internal medicine, cardiology, obstetrics and gynecology, plastic surgery, do not believe that the rulemaking will serve the health and safety of women and has the following concerns:

(1) SHPC requests an extension of the comment period and a public hearing. In support of these requests SHPC argues that 60 days is too short a period to adequately respond to the rulemaking; that the studies cited in the rulemaking are not readily available to the public, are lengthy and require careful review; and that the Board's and subcommittee meeting minutes are not available. Citing the public need for transparency, SHPC requests a public hearing, claiming that such hearings were held in the past when considering the appropriateness of the rules governing termination of pregnancy and that expert testimony is needed to fully understand the subject and the impact of the rulemaking.

(2) SHPC argues that the Board does not provide any statistical or other factual data in support of the assertion that New Jersey residents lack access to abortion and cites the Guttmacher Institute, finding that New Jersey, as compared to other states, has few restrictions on access to abortion services and 76 abortion providers. SHPC also notes that although the Board's existing rules allow it to review circumstances of abortions requiring increased skill and receive reports of complications, there is no discussion of any information obtained from these reports. SHPC states national data on abortion is incomplete; that there are no national reporting requirements, and data collected by the CDC is provided on a voluntary basis and even Guttmacher Institute acknowledges that its studies have shortcomings due to available data; and, therefore, it is essential for New Jersey to gather this data in order to make an informed decision in this area.

(3) SHPC next states that redefining surgery will have unintended consequences that reduce patient safety. It criticizes the decision to change definitions of minor surgery to minor procedures because, it argues, taking out two listed examples of surgery, such as "curettage of tissue" and "extraction of tissue from the uterus" creates ambiguity, because these procedures otherwise fall within the Board's definition of surgery ("a manual or operative procedure performed upon the body"), as well as the American Medical Association's and American College of Surgeons' (ACS) definition. The MBOD states that (1) aspiration abortion falls within this definition because it is a manual procedure; using a canula placed into the uterus to suction out the fetus and the placenta; and (2) changing the definition of minor procedure, by

removing the two examples listed above creates an ambiguity as to where other gynecological procedures, such as myomectomy and polypectomy and treatment for endometriosis fall. The MBOD also argues that such a description does not alter the need for the use of anesthesia that may be indicated based on a patient's medical status and pain management preferences, criticizing the notice of proposal's lack of distinction between the different types of procedures/surgeries according to the level of anesthesia. In addition, SHPC states that the abortion industry has long acknowledged aspiration and D&E abortion procedures as "surgical abortions," citing CDCs Abortion Surveillance System FAQs at http://www.cdc.Gov/reproductivehealth/data_stats/abortion.htm, stating that "Most states and reporting areas that collect abortion data now report if an abortion was medical or surgical. Medical abortions are legal procedures that use medications instead of surgery."

(4) SHPC next argues that ACOG-recommended changes to the definitions do not match the State's regulatory framework, and that the purpose of ACOGs recommendation is to declassify certain procedures to help to clarify which procedures it believes should be delegated to APCs under the order or supervision of a physician rather than to be performed directly by an APC; that such classification is not based on the location at which the procedure is performed or the level of anesthesia used, while the proposed definition of "minor procedure" is conditioned on the level of anesthesia used. SHPC argues that maintaining the current regulation is necessary because it applies to all minor surgeries in the State and by changing the definition the Board is reducing the level of protection afforded patients and causing confusion to medical specialties. SHPC also is concerned by the proposed new definition of "early aspiration abortion," which it argues should be amended to (1) delete the reference to trimester and replace it with stated weeks of gestation-since, SHPC claims, it is well established that the length of gestation determines proper practice, procedure, and standard of care for medical care to pregnant women; and (2) eliminate confusion arising from the definition's defining all abortions up to 12 weeks gestation as "minor procedures" without any reference to anesthesia. In support SHPC refers to the NASEM report, which states that "People differ in their experience of and tolerance for pain ... NAF recommends that providers involve women in the analgesia/sedation/anesthesia decision and the choice be made on the patient's needs and assessments of the risks and benefits (NAF, 2017(a)).

(5) SHPC is also concerned about reduction in minimum standards by permitting APCs to perform surgical abortions. It argues that the Board's goal of increasing access by permitting APCs to perform early aspiration abortion cannot be accomplished by the Board's rulemaking alone and will require action taken by the Legislature and impacted licensing boards. In support of their argument, SHPC refers to the NASEM report and the ACOG position, which it claims is clearly conditioned on whether APCs are adequately trained and demonstrate the appropriate level of competence and is not blanket support for allowing APCs to perform aspiration abortion, as the Board is proposing. Furthermore, SHPC claims that the NASEM report describes a lack of training in abortion procedures in curriculum requirements even for physicians and ACOG recognizes that no such curriculum exists for APCs and must be developed. With regard to the Board's reliance on the UCSF medical center study, SHPC notes that in accepting the study's recommendations, the California legislature codified requirements for education and training, and limited the scope of procedures for APCs before they were permitted to perform first trimester aspiration abortion (See Cal Bus & Prof Code 2725.4). Reviewing the meeting minutes of the Midwifery Liaison Committee and the New Jersey Board of Nursing, SHPC notes that there is no indication whether these boards have considered whether or not legislation is needed to expand their scope of practice or even if there is support from these licensing boards for an expanded scope of practice. Even if there is no [page=2035] legislation required for this expansion, it argues, these boards will still need to promulgate rules to expand the scope.

(6) SHPC argues that by deleting N.J.A.C. 13:35-4.2(h), the Board eliminates the requirement that fetal tissue be properly disposed of and this requirement should be left in because proper disposal ensures that fetal tissue is not illegally stored or sold. SHPC cites *Box v. Planned Parenthood of Ind. & Ky., Inc.*, 139 *Ct.* 1780, 1782; 204 *L.Ed.* 2d 78, 80 (2019) for the proposition that a state has a legitimate interest in the proper disposal of fetal remains.

RESPONSE: (1) The Board does not believe that there is any need to extend the comment period or conduct a public hearing. SHPC's assertion that the comment period was too short is belied by the fact that the Board received more than 2,000 comments from individuals and organizations and that SHPC's was the only comment period extension request. Additionally, SHPC did not describe why two months would be insufficient time to review the studies cited in the rulemaking.

With regard to the assertion that the cited studies are not readily available: the Board has confirmed that all studies mentioned in the rulemaking are readily available to the public. The Board notes that the rulemaking contained an incorrect internet link following the citation to ANSIRH's study, " *State Law Approaches to Facility Regulation of Abortion and Other Office Interventions."* Specifically, the link in the proposal leads to a different ANSIRH article. Nevertheless, the correct citation precedes the incorrect link in the proposal, and a search for that citation yields the correct article on the Internet. Additionally, the correct link is as follows: http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2017.304278.

With regard to unavailability of minutes of Board and subcommittee meetings: the Board is aware of a delay in the posting of Board meeting minutes to the Board website. Specifically, minutes of Board meetings that occurred from October 2019 through January 2021 were not posted to the Board's website. This delay is attributable to staffing shortages that existed prior to and during the first nine months of the COVID-19 pandemic. The Board regrets this delay in making updates to its website but notes that it applies generally to meetings that occurred during that time period, not just this rulemaking. Additionally, despite the unavailability of some meeting minutes on the website, the Board has fully complied with the Administrative Procedure Act's notice requirement for rulemaking at N.J.S.A. 52:14B-3, including affording a 60-day comment period, giving the public and this commenter sufficient time for awareness and to fully respond. With regard to SHPC's request for a public hearing, the Board is not aware of any additional information that could be conveyed in a hearing that could not be, or has not been, included in commenters' written submissions. N.J.S.A. 52:14B-4(a)(3) states that a State agency shall "conduct a public hearing on the proposed rule at the request of a committee of the Legislature... if sufficient public interest is shown," and goes on to state that "the head of each agency shall adopt as part of its rule of practice adopted pursuant to section 3 of P.L. 1968 c. 410 (C.52:14B-3) definite standards of what constitutes sufficient public interest for conducting a public hearing." The Division of Law and Public Safety, within which the Board of Medical Examiners falls, has promulgated N.J.A.C. 13:1E-4.3(b)1 and 2, which defines "sufficient public interest" as at least 50 persons submitting written requests to hold a public hearing "to present data, arguments or views that raise a substantial issue as to the impact of the proposal on the regulated community or the general public that has not been anticipated by the agency." Pursuant to N.J.A.C. 13:1E-4.3(c), professional organizations or a law firm requesting a hearing on behalf of a group or interested parties is to be considered one person. SHPC's request for a public hearing does not constitute "sufficient public interest." Pursuant to N.J.A.C. 13:1E-4.3(c), SHPC is to be counted as one person, resulting in one total request, which does not meet the 50-person threshold triggering the requirement. Finally, the arguments made by SHPC do not raise any substantial issues that were not anticipated by the Board; in fact, the rulemaking itself squarely addresses the issues raised in SHPC's

comment and explains the basis, in detail and with citations, for concluding that the rulemaking will improve the public health, safety, and welfare.

(2) With regard to SHPC's assertion that there is no need to expand access to care in New Jersey, it is not essential to the Board's consideration whether New Jersey's current rules surrounding abortion impose fewer barriers to care than the laws, rules, and regulations of some other states, particularly when other jurisdictions' restrictions are imposed legislatively instead of being adopted based on the judgments of a professional licensing board. Rather, the Board is focused on ensuring access to quality care by removing unnecessary restrictions on medical procedures. With regard to SHPC's reference to reports of certain abortions required to be made to the Board and the data on which national-level studies are based: The Board has relied on the best available national level studies and data. These studies and data are more comprehensive and robust than reports made to the Board. For more information regarding the studies on which this rulemaking is based, see the Response to Comment 40.

(3) The Board disagrees that removing reference to curettage and extraction of tissue will cause confusion. The Board's modification aligns with ACOG's January 2018 position statement, and as stated in the notice of proposal Summary, the Board makes this rule change to "eliminat[e] ... the implication that abortions beyond the first trimester constitute "surgery"." The Board believes practitioners will easily understand the distinction between this definition and the medication vs. surgical abortion dichotomy. See also, the Response to Comment 53. With regard to concerns about distinctions between levels of anesthesia: the Board, relying on its own expertise, has assessed the risks of a variety of procedures, including early aspiration abortions and made its determination that risks are greater depending on the level of anesthesia used. With regard to abortion, assessing the type of procedure, and the gestational period, the Board has accordingly tailored requirements to address those risks.

(4) With regard to SHPC's reference to ACOG standards and proposed amendments to the definition of "early aspiration abortion" see the Response to Comment 26.

(5) With regard to concerns about APC training and the quality of abortion care provided by APCs, see the Response to Comment 43 and the Response to Comment 31, paragraph 6.

(6) With regard to SHPC's concerns about removal of regulatory requirements pertaining to fetal tissue, see the Response to Comment 91.

36. COMMENT: Commenters, including a group of 45 medical practitioners, write in opposition to the rulemaking. They state that the NASEM report's abortion statistics are incomplete because many states do not have mandatory reporting and that abortion providers are often not aware of complications arising from procedures, because many patients seek care in emergency rooms rather than with the abortion provider and do not inform the provider of that follow up care. The group of 45 medical practitioners also state that APCs should not be allowed to perform abortions because they do not possess the skills and experience necessary to identify and manage complications. They also argue that to call aspiration abortions "minor procedures" instead of "minor surgeries" would only serve to misinform women who are considering abortions, since women need to know the surgical nature of abortion procedures fully and might not be content with non-physicians performing such procedures.

This group is opposed to the Board's permitting abortion procedures in office settings, removing privileging requirements at nearby hospitals, and eliminating the requirement of mandated reporting of complications from first trimester abortions, as currently required, because they argue that undermine

women's safety when accountability is diminished. Finally, the group argues that the Board will not be acting within its responsibility to protect the health and safety of women if they permit these amendments.

RESPONSE: The Board notes that contrary to the commenters' assertion, 46 states and the District of Columbia require hospital facilities and physicians that perform abortions to submit regular, and confidential, reports, and 28 states require providers to report post-abortion complications. http://www.guttmacher.org/state-policy/explore/abortion-reporting-requirements#. Although such reporting is not required in New Jersey, New Jersey data is reflected in generally accepted compendiums of abortion statistics. Specifically, the NASEM report utilizes two primary sources of national and state-level abortion statistics: CDC's Abortion Surveillance System and Guttmacher Institute's Abortion Provider Census (GI census). Nat'l Academies of Sciences, Engineering, and Medicine, *supra*, at 22-23. Although reporting [page=2036] to the CDC is voluntary, only three states, California, Maryland, and New Hampshire, did not provide information in 2016 (the year the data relied upon by the NASEM report was submitted), and GI's census solicits information from all providers in the country, including those that do not provide information to the CDC. For example, the NASEM report notes that the CDC's 2013 abortion surveillance report references at least 70 percent of the abortions reported by the GI's Census that year. *Id*. at 26.

In assessing the current safety record of abortions, the Board reviewed research, including the many studies assessed in the NASEM report. For example, Advancing New Standards in Reproductive Health (ANSIRH) is a collaborative research program at the Bixby Center for Global Reproductive Health, in the Department of Obstetrics, Gynecology, & Reproductive Sciences at the University of California, San Francisco (UCSF). ANSIRH analyzed approximately 55,000 abortions and any subsequent health care at any clinical site, including emergency rooms and hospitals, up to six weeks after the procedure. The study found, among other things, that (1) less than a quarter of one percent (0.23 percent) of abortions in the study resulted in a major complication (defined as serious, unexpected events requiring a blood transfusion, surgery, or hospital admission); (2) less than one percent of abortions resulted in a complication that was diagnosed and treated in an emergency room; and (3) the complication rate found in the study is similar to previous research, even with emergency room visits and other sources of care. *Safety of Abortion in the United States* (ANSIRH Issue Brief #6, December 2014), http://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf.

The Board also believes physicians should be able to authorize APCs to perform early aspiration abortions. In support of its position the Board points to multiple studies reviewed in the NASEM report, including the largest and leading study in patient safety data in California, which found comparable levels of safety between newly trained APCs and physicians in performing early aspiration abortions. Tracey Weitz, et al., *supra*, at 454. Also see the Response to Comments 40 and 47.

The Board does not believe that identifying early aspiration abortion as a "minor procedure" will mislead or misinform the public. The change in terminology proposed by the Board is supported by up-to-date, evidence-based research, reports and studies, which concluded that the risks and complexities of early aspiration abortion are similar to other procedures that the Board has previously determined do not require or warrant compliance with the heightened regulatory standard of N.J.A.C. 13:35-4A (such as hospital privileging requirement and mandated reporting). Further, this rulemaking is consistent with ACOG's position statement, which defines "procedure" in the context of obstetrics and gynecology, as a "[n]on-incisional, diagnostic or therapeutic intervention through a natural body cavity or orifice." ACOG, "Definition of 'Procedures' Related to Obstetrics and Gynecology" (January 2018). Therefore, removing

the additional restrictions on early aspiration abortions, such as privileging requirements and mandated reporting of complications is appropriate, given the simplicity and safety record of this procedure. Finally, the Board believes that abortion procedures can be safely provided in an office setting like medical procedures with comparable complexity and risk and that there is no medical necessity to treat abortions differently. The NASEM report, reviewed by the Board, concluded that the four most common methods of abortion; medication abortion, aspiration, D&E, and induction abortions are safe and effective with very rare serious complications and that most abortions can be safely provided in office settings, and that the need for facility upgrades or equipment mandates are more dependent on the level of sedation utilized. Nat'l Academies of Sciences, Engineering, and Medicine, *supra*, at 10, 26. Additionally research by ANSIRH concluded that requiring all abortion procedures to be performed in ASCs vs. office settings did not provide any benefits to patient safety or experience, but rather reduced access to care. "State Law Approaches to Facility Regulation of Abortion and Other Office Interventions, OBS Laws vs. TRAP laws" (ANSIRH, Oakland, C.A.) Feb. 2018. (Advancing New Standards in Reproductive Health (ANSIRH) is a collaborative research program at the Bixby Center for Global Reproductive Health, in the Department of Obstetrics, Gynecology, & Reproductive Sciences at the University of California, San Francisco (UCSF).)

Although the Board acknowledges that unexpected complications can arise any time during any medical procedure, the Board also believes, in the context of this rulemaking, that abortion procedures should be regulated like medical procedures with comparable complexity and risk and that there is no clinical or medical justification, based on the current state of research, to do otherwise.

37. COMMENT: One commenter states that the NASEM report's claim that abortions are safe compared to comparable procedures is misleading because it is not based on impartial data from a long-term, comprehensive tracking of women with one or more abortions and women who had none, and that no study has yet been done to accurately determine the long-term effects of abortion on women's physical and mental health. This commenter also contends that by using statistics and research provided by Guttmacher Institute (GI), the NASEM report is not credible because this information is biased, since GI is connected to Planned Parenthood.

RESPONSE: Abortion is a legal medical procedure in New Jersey and the right to an abortion is constitutionally protected. The goal of this rulemaking is to modernize the Board's existing regulatory framework, which currently singles out, without medical or clinical basis, abortion as a stand-alone procedure, and to ensure that the regulations do not harm public health by creating barriers to abortion care. Based on the peer-reviewed, evidence-based research and studies it has reviewed, the Board has determined that abortion procedures have very rare complications; that early aspiration abortions need not be restricted to being performed only by physicians; and that post-first-trimester abortions are special procedures that should be regulated under the current provisions at N.J.A.C. 13:35-4A (Rule 4A). The Board also notes that contrary to the assertion that there are no studies on the effects of abortion on the mental and physical health effects on women, the NASEM report contains a thorough analysis of epidemiological research examining the long-term physical and mental health effects of undergoing abortions. Specifically, the NASEM report examines the available evidence in four commonly alleged areas of harm: (1) future negative childbearing and pregnancy outcomes, such as (a) secondary infertility; (b) ectopic pregnancy; (c) spontaneous abortion and stillbirth; (d) complications of pregnancy; (e) preterm-birth; (f) small for gestational age; and (g) low birthweight; (2) risk of breast cancer; (3) mental health disorders; and (4) premature death. The analysis determined that an abortion does not increase the

risk of secondary infertility, pregnancy-related hypertensive disorders, abnormal placentation (after a D&E abortion), preterm birth, breast cancer, or mental health disorders, such as depression, anxiety, and Post-Traumatic Stress Disorder. *The Safety and Quality of Abortion Care in the United States* (The National Academies Press, 2018) at 129-153, http://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states.

The Board also maintains that all studies, research, and reports relied upon are peer-reviewed and evidence-based and that the Board did not rely on any one single study in developing this rulemaking, but rather on the collective research available, as well as the experience and expertise of the Board.

38. COMMENT: One commenter states that the NASEM report cited in the rulemaking has a pro-abortion bias that is evidenced by its failure to describe what happens to the fetus during an abortion procedure. Specifically, this commenter states that the report fails to describe the "initial step" of an induction abortion, which the commenter describes as "the killing of a fetus in the womb by a lethal injection of digoxin or potassium chloride solution, which causes the fetus to have a cardiac arrest."

RESPONSE: The Board notes that the NASEM report addresses the safety of abortion procedures as it relates to patient complications, morbidity, and mortality rates. The scope of this rulemaking, and the mandate of the Board within this scope, is to ensure the health, welfare, and safety of the patient. To that end, the Board is proposing to modernize its rules pertaining to legal abortion procedures by eliminating provisions that are medically unnecessary and create barriers to abortion care. Upon reviewing modern scientific and evidence-based research, such as the NASEM report, the Board has determined that legal abortion procedures should be regulated like medical procedures with comparable complexity and risk, requiring similar safeguards. Further, abortion is a legal medical [page=2037] procedure in New Jersey and a Constitutionally protected right-and as such, like any legal medical procedure -- the Board periodically reviews and amends its rules to align with up-to-date scientific evidence.

39. COMMENT: New Jersey Catholic Conference (NJCC) writes to express its opposition to the rulemaking and requests that the Board not adopt its rulemaking. The NJCC believes that any policy that threatens the right to life is an attack on the foundation of all other human rights. It argues that the Board's current regulations do not limit access to abortion procedures, citing the Guttmacher Institute report that over 48,000 abortions were performed in New Jersey in 2017, which accounted for 5.6 percent of abortions performed in the nation. It adds that between 2014 and 2017 the abortion rate in New Jersey increased by nine percent while the national rate decreased by eight percent. NJCC further argues that because New Jersey does not have any major restrictions on abortions, and because taxpayer money is allocated for these services, the Board's rulemaking is arbitrary and capricious and not based on medical necessity.

RESPONSE: Abortion is a legal procedure in the State of New Jersey and the right to an abortion is Constitutionally protected. The Board has the mandate to protect the health, welfare, and safety of the public by promulgating rules governing the provision of abortion in this State. In keeping with this mandate the Board has determined, through a comprehensive review of up-to-date evidence-based research that current provisions relating to abortion procedures are medically unnecessary. For instance, requiring "physicians only" to perform early aspiration abortion has been shown to be a medically unnecessary restriction, because large, comprehensive studies have shown that APCs can provide early aspiration abortion just as safely and effectively. Tracey Weitz, et al., *supra*, at 454. Further, the data cited in reference to the abortion rate in New Jersey does not reflect the number of individuals who would

have opted to have an abortion but could not obtain one because of the current, medically unnecessary restrictions in place.

40. COMMENT: One commenter questions whether, in addition to research performed by Planned Parenthood of New Jersey (PPNJ), there has been impartial research into the safety of abortions. This commenter states that PPNJ has a special interest in this topic and, therefore, any research done and/or funded by PPNJ is not credible and, therefore, should not be trusted.

RESPONSE: The Board points out that in considering and proposing the current repeal, amendment, and new rules, in addition to relying on its own expertise, the Board did not rely on any one single study but rather on a comprehensive review of current research including: (1) the NASEM report, The Safety and Quality of Abortion Care in the United States, (The National Academies Press, 2018). http://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states, a comprehensive review based on evidence gathered from randomized controlled trials comparing various approaches to abortion care, systematic reviews, meta-analyses retrospective cohort studies, case control studies, and other types of observational studies and patient and provider surveys of the state of science on the safety and quality of legal abortion in the nation. The study concluded that the four most common methods of abortion-medication abortion, aspiration, D&E, and induction abortions-are safe and effective with very rare serious complications, that most abortions can be safely provided in office settings, and that the need for facility upgrades or equipment mandates are more dependent on the level of sedation utilized. (2) CDC's Abortion Surveillance report finding that in 2016, approximately 91 percent of abortions were performed within 13 weeks of gestation and that aspiration abortion was the most common method, taking only a few minutes to complete and typically administered without anesthesia. Tara C. Jatlaoui, et al., *Abortion Surveillance-United States, 2016*, Morbidity and Mortality Weekly Report, Nov. 29, 2019, at 1, 26, http://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6811a1-H.pdf. (3) Advancing New Standards in Reproductive Health (ANSIRH)'s research report, "State Law Approaches to Facility Regulation of Abortion and Other Office Interventions, OBS Laws vs. TRAP laws" (ANSIRH, Oakland, C.A.) Feb. 2018, which concluded that requiring all abortion procedures to be performed in ASCs vs. office settings did not provide any benefits to patient safety or experience, but rather reduced access to care. (4) Sarah C. M. Roberts, et al., *Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions*, 319 JAMA 2497 (2018); Nancy F. Berglas, et al., *The Effect of Facility Characteristics on Patient Safety, Patient Experience, and Service Availability for Procedures in Non-Hospital-Affiliated Outpatient Settings: A Systematic Review*, 13 PLoS One (2018). (5) ACOG's Committee Opinion No. 612 on abortion training and education, recommending the expansion of the trained pool of non-obstetrician-gynecologist, to include family physicians and APCs by including first trimester abortion training in APC's curriculum and eliminating "physicians only or obstetricians-gynecologists only" restrictions to the provision of abortion care. (6) ACOG's January 2018, position statement on the *Definition of 'Procedures' Related to Obstetrics and Gynecology*," asserting that abortions are more appropriately termed as "procedures" rather than surgery. http://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/definition-of-procedures-related-to-obstetrics-and-gynecology. (7) The American Public Health Association's Policy Statement, *Provision of Abortion Care by Advanced Practice Nurses*" which concludes that both physicians and APCs can provide medication and aspiration abortions safely and effectively. American Public Health Association, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants*, Policy Statement Database (Nov. 1, 2011), http://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-

database/2014/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants#Anchor%201. (8) "Safety of Aspiration Abortion performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under A California Legal Waiver," the largest and leading study currently, which examined data relating to 11,487 patients, in California after APCs were allowed to provide early aspiration abortions, concluding that complication rates from these procedures performed by newly-trained APCs were clinically equivalent to complication rates when performed by experienced physicians. Tracey Weitz, et al., *Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under A California Legal Waiver*, 103 Am. J. of Pub. Health 454, 454 (2013).

41. COMMENT: Commenters argue that the Board's rulemaking is the result of successful lobbying by special interest groups within the abortion service industry who seek to profit monetarily. These commenters believe that the proposed repeal and amendments, therefore, are not motivated by the intention to protect the health and safety of women. RESPONSE: The Board is mandated by law to protect the health, safety, and welfare of the public. The Board notes that it frequently evaluates research, credibility, and competing interests of the many advocates who come before it with requests of all sorts. The Board recognizes abortion is an essential element of comprehensive reproductive health care and here proposes an updated, integrated, and evidence-based regulatory approach specifically designed to fulfill its mandate to protect the health, safety, and welfare of the public. The Board further notes that abortion is legal medical care in New Jersey and the right to abortion is Constitutionally protected.

42. COMMENT: One commenter states that the Board makes a false assertion based on biased studies that most abortions happen within the first 13 weeks and that complications are very rare. The commenter states that the rulemaking is not meant to remove barriers to care, but rather to reduce the expenses incurred by entities providing abortions, which will increase the number of abortions and increase profit margins.

RESPONSE: In 2018, NASEM's Committee on Reproductive Health Services (NASEM Committee) undertook a comprehensive review of the state of research on the safety and quality of legal abortion and found that clinical evidence suggests that serious complications occur in somewhere between fewer than one percent and five percent of abortions-whether by medication, aspiration, Dilation and Evacuation, or induction -- with the risk of a serious complication increasing with the number of weeks gestation. Nat'l Academies of Sciences, Engineering, and Medicine, *supra* at 10, 26, 77-78, http://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states. The vast majority--over 90 percent--of abortions occur within the first 13 weeks of gestation with fewer than nine percent performed after 13 weeks gestation. *Id.* at 29. The Board further notes that this rulemaking is intended to modernize the regulatory framework for abortion procedures according to science and evidence-based, up-to-date research, and studies, such as the above, which suggests that abortion procedures are safe and that the existing [page=2038] regulatory structure is not only medically unnecessary but creates barriers to access to care.

43. COMMENT: One commenter states that abortion safety data and statistics in the resources and studies cited in the rulemaking are misleading with regard to APCs' ability to perform abortions and whether certain abortion procedures should be allowed to be performed in an office setting. The commenter argues that the results of the studies are a reflection of abortion safety based on current providers' competency in currently permissible treatment settings.

RESPONSE: The Board notes that, contrary to the commenter's assertion, in addition to relying on its own expertise, the Board considered direct evidence of patient safety in aspiration abortions performed by APCs. The Board, in fact, reviewed the largest and leading study in patient safety data in California, which found no clinically significant difference in complication rates between newly trained APCs and experienced physicians, in performing early aspiration abortions. Tracey Weitz, et al, *supra*, at 454. This study analyzed data from 11,487 early aspiration abortions performed by APCs, over the course of three years. *Id.* Further, the NASEM report, also reviewed by the Board, analyzed two additional smaller studies comparing the outcomes of aspiration abortions performed by APCs and physicians that did not find any statistically significant difference in complication rates, leading to the conclusion that aspiration abortions were performed safely and effectively by APCs with a high degree of patient satisfaction. Nat'l Academies of Sciences, Engineering, and Medicine, *supra*, at 103-105. http://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states. With regard to the commenter's concerns regarding abortions being performed in an office, modern research has not found any patient safety benefits to having abortion procedures performed in ASCs versus in an office; evidence shows that, as accomplished by the Board's proposal, safeguards in office settings are more appropriately based in part on the level of anesthesia used, rather than on the fact that the procedure being performed is an abortion. To that end, Rule 4A ensures that offices are properly equipped. *Supra*. at 10, 26, 77-78. http://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states.

44. COMMENT: Several commenters contend that this rulemaking is politically motivated to support Governor Murphy's administration's agenda to increase abortion access in the State and is an attempt to legislate without having to go through the Legislature.

RESPONSE: The Board notes that the rules proposed to be repealed and amended (that is, Rule 4.2 and Rule 4A) were promulgated and amended through the years by the Board pursuant to its statutorily granted rulemaking authority. Absent a statute to the contrary, the Board has the full authority to propose, repeal, and amend its own rules. Thus, this rulemaking is within the Board's purview. As to the motivation of the rulemaking, the Board is informed by recent case law scrutinizing and invalidating several instances of targeted rules of abortion providers, along with medical and clinical advancement in the field of abortion care, which suggest that abortion procedures are safe and should be regulated like any other medical procedure with comparable complexity and risk. In December 2018, the Board empaneled a subcommittee to review the Board's existing abortion laws, and after a comprehensive review of up-to-date, evidence-based and peer-reviewed resources, as cited in the rulemaking summary, the Board determined that it was appropriate to treat abortion procedures like other medical procedures of comparable complexity and risk, and that doing so may increase timely access to safe medical care. In addition, the subcommittee sought input from the New Jersey Department of Health during its review. For additional detail on the studies and research relied upon by the Board, see the Response to Comment 40.

45. COMMENT: One commenter believes that the rulemaking will not improve access to abortion, which already exists, and that the only consequence of this rulemaking will be to develop more political divisiveness and degrade, rather than improve, women's health. This commenter believes the rulemaking is politically motivated to establish the Board as a politically progressive entity.

RESPONSE: The Board is mandated to protect the health, welfare, and safety of the public in general and, in the context of this rulemaking, the health, welfare, and safety of patients undergoing abortions. Contrary to the assertion of the commenter, the Board is motivated not by political concerns, but rather by

the evidence-based research it has reviewed, and which has led it to modernize and update its regulatory framework concerning abortion procedures, and to remove barriers to abortion care that are medically unnecessary and bring its rules in conformance with now-recognized constitutional protections. For additional detail on the studies and research relied upon by the Board, see the Response to Comment 40.

46. COMMENT: Commenters who oppose the rulemaking state their belief that that access to abortion exists, stating that New Jersey has "some of the least restrictive abortion laws" (citing FindLaw, New Jersey Abortion Laws - FindLaw, available at http://statelaws.findlaw.com/new-jersey-law/new-jersey-abortion-laws.html). Commenters also state that New Jersey has the highest rate of abortion in the nation, more than twice the national average; that in 2017 there were 76 operating abortion clinics and 41 abortion providing clinics; and that two-thirds of New Jersey counties have abortion facilities and 76 percent of women live in those counties. One commenter also adds that in 2017, 48,110 abortions were performed, 5.5 percent of which occurred in New Jersey, despite New Jersey being one of the smallest states in the nation citing to "Abortion Incidence and Service Availability Incidence and Service Availability in the United States," 2017, NY (2019) by Jones RK, Witmer, and Jerman J.

RESPONSE: The objective of the rulemaking is to modernize the regulatory framework relating to abortion care in the State by removing medically unnecessary provisions that serve as barriers to abortion care. Current evidence-based research and peer reviewed studies reviewed by the Board strongly indicate that abortion procedures should be treated like other medical procedures of comparable complexity and risk, and that the quality of medical care is not improved by maintaining existing restrictions and provisions, which are medically unnecessary and do not improve the public's health, welfare, and safety. Further, the Board notes that it has not relaxed rules that are medically necessary, nor has it eliminated any patient safeguards that it has deemed necessary or beneficial to patient health; all safeguards that apply to "special procedures" that are comparable to post-first-trimester abortion, as defined within Rule 4A, remain in place. It is not essential to the Board's consideration that New Jersey's current rules surrounding abortion impose fewer barriers to care, than the laws and regulations of some other states, nor is it appropriate for the Board to comment on whether the rate of a legal medical procedure in this state is "too high" or low, so long as the safety, health, and welfare of the patient undergoing the medical procedure, in this particular instance, is protected.

47. COMMENT: One commenter refers to the Tracey Weitz article cited in the rulemaking, and states that the commenter is concerned by the statistic provided within the article that studies have found twice the rate of complications for APCs performing abortions as for physicians. This commenter further adds that in countries with limited resources this statistic is acceptable, but it is not acceptable here.

RESPONSE: The study to which commenter refers, "Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver," is a prospective, observational cohort study published as a peer-reviewed article in *The American Journal of Public Health.* As described in the Response to Comments 36 and 40, the study evaluated 11,487 aspiration abortions to assess "whether the effect of a new treatment [the provision of aspiration abortion by NPs, CNMs, and PAs] is not worse than that of an active control [provision of aspiration abortion by physicians] by more than a specified clinically acceptable margin." The study concluded that results indicated that the "complication rates from aspiration abortions performed by recently trained NPs, CNMs, and PAs were statistically no worse than those from those performed by the more experienced physician group." The article further noted that both provider groups (advance practice clinicians and

physicians) "had extremely low numbers of complications, less than 2% overall--well below published rates--and only six complications out of 11,487 procedures required hospital-based care."

48. COMMENT: Commenters state their moral and or religious objection to abortion itself and their belief that life begins at conception and that abortion is, therefore, murder. Based on this premise, commenters [page=2039] question how the Board can support abortions when, as physicians, Board members take the Hippocratic Oath to protect human life and do no harm.

RESPONSE: Abortion is legal medical care in the State of New Jersey and the right to abortion is Constitutionally protected.

49. COMMENT: Commenters stated that women who have abortions suffer from subsequent emotional trauma including suicide, addiction, depression, and physical harm, and that, therefore, all abortion procedures are harmful to the health, safety, and welfare of women.

RESPONSE: Legally obtained abortion is one of the safest procedures today. Abortion is legal medical care in the State of New Jersey and the right to abortion is Constitutionally protected. As with all medical procedures, the determination whether to proceed with an abortion is one that must be made by the patient, ideally in a manner that weighs many factors, including the benefit to the patient and the risks involved in the procedure. Providers are required to adhere to standards of care, obtain informed consent and provide relevant, accurate, and timely medical information to patients when performing all medical procedures. Access to abortion is an essential element of comprehensive reproductive health care. For a more comprehensive discussion regarding the alleged harms that the commenters have referred to, see the Response to Comment 37.

50. COMMENT: One commenter does not agree that the word "care" should follow "abortion" in the language of the notice of proposal Summary. This commenter believes that abortion procedures are not "care" for the patient or the fetus.

RESPONSE: Abortion, or the induced termination of pregnancy, is a legal medical practice offered by licensed health care providers in the State of New Jersey.

51. COMMENT: Commenters state their belief that Governor Murphy supports a "culture of death" and acts hypocritically in mourning the death of COVID-19 victims but not the death of aborted fetuses.

RESPONSE: As described in the rulemaking, the Board empaneled a subcommittee, in December of 2018, to examine the Board's abortion rules. The rulemaking published was the culmination of the comprehensive review conducted by the Board. Additionally, the Board disagrees with the commenters' characterization of the actions of the Governor.

52. COMMENT: Commenters claim that fetuses feel pain after 20 weeks LMP.

RESPONSE: Abortion is a legal medical procedure in the State of New Jersey and the right to abortion is Constitutionally protected. The scope of this rulemaking and the scope of the mandate of the Board is the protection of the health, welfare, and safety of the patient who is undergoing an abortion procedure. As with every other legal medical procedure, the Board's duty is to ensure safety and health. In this rulemaking, the Board is motivated by science and evidence-based research which conclude that abortion procedures should be regulated like similar medical procedures in complexity without medically unnecessary rules, which create barriers to access to care to the public. To that end the Board is proposing

to repeal N.J.A.C. 13:35-4.2 and incorporate later term abortions as "special procedures" under the safeguards at N.J.A.C. 13:35-4A.

53. COMMENT: Commenters state that the change to define first-term abortion as a "minor procedure" is wrong and a misnomer because fetal death occurs as a result of every abortion. Some commenters also argue that early aspiration abortions are not "minor procedures" but rather "invasive surgical procedures."

RESPONSE: The Board notes that its change to define early aspiration abortion as a "minor procedure" was determined after a thorough review of up-to-date, evidence-based research, reports and studies, which concluded that the risks and complexities of early aspiration abortion are similar to other procedures that the Board has previously determined do not require or warrant compliance with the heightened regulatory standard at Rule 4A. Further, this change is consistent with ACOG's January 2018 position statement, which defines "procedure" in the context of obstetrics and gynecology, as a "[n]on-incisional, diagnostic or therapeutic intervention through a natural body cavity or orifice." Finally, the Board notes that abortion is legal in the State of New Jersey and that the right to abortion is Constitutionally protected.

54. COMMENT: Two commenters contend that the Board's rulemaking will result in, and sanction, "back alley" abortions.

RESPONSE: The Board's rulemaking is designed among other things, to diminish the likelihood that any New Jersey patient would ever need to resort to a "back alley" or "illegal" abortion. Legal abortion is one of the safest medical procedures. Increasing access to trained providers offering timely, safe access to legal abortion is an established strategy to prevent patients from seeking illegal abortion. Updating the rules as they pertain to abortion procedures in this State will enhance the health, safety, and welfare of the public by improving access to care for patients who need it and by removing medically unnecessary rules. Additionally, the safeguards present for all legal medical procedures with comparable complexity and risk, performed in an office setting pursuant to N.J.A.C. 13:35-4A will remain in effect.

55. COMMENT: One commenter states that abortions are not simple procedures.

RESPONSE: The Board considered the varying complexity of induced abortion at different stages of pregnancy. Among other things, the Board reviewed clinical practice guidelines for abortion care, including those referenced in the NASEM report. To the extent certain abortions are considered "special procedures," they will be subject to rules applicable to all special procedures.

56. COMMENT: One commenter argues that important and necessary protections for women will be removed if the rulemaking is adopted.

RESPONSE: The Board notes that research and studies consulted and cited within the rulemaking summary have shown that the risk of complications when APCs perform first-trimester abortions is low, that there is no clinically significant difference in the rate of complications arising between abortions performed by APCs and physicians, and that there are no patient safety benefits to having abortion procedures performed in ASCs versus in an office. The NASEM report concludes that based on clinical evidence, serious complications occur in fewer than one percent of abortions, whether by medication, aspiration, Dilation and Evacuation, or induction, and that this risk does not exceed five percent with the risk of complications increasing with weeks' gestation. *Supra*. at 10, 26, 77-78, http://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states. Finally, evidence shows that, as accomplished by the Board's rulemaking, safeguards in office settings are more

appropriately based, in part, on the level of anesthesia used rather than on the fact that the procedure being performed is an abortion. *Id*.

57. COMMENT: One commenter, who is an obstetrician-gynecologist, contends that complications from abortion procedures are more common and more challenging to treat than is believed, and that the commenter's years of experience treating post-abortion complications like hemorrhage and infection have informed the commenter's belief that even with years of experience, treating complications of post-abortion hemorrhage or infections is challenging.

RESPONSE: The Board thanks the commenter for sharing the commenter's experience. The Board also notes, however, that the comprehensive evidence-based research consulted show that complication rates after a legal abortion procedure are very low. The NASEM report concludes that based on clinical evidence, serious complications occur in less than one percent of abortions, whether by medication, aspiration, Dilation and Evacuation, or induction and that this risk does not exceed five percent with the risk of complications increasing with weeks' gestation. *Supra*. at 10, 26, 77-78, http://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states.
Specifically, with regard to complications such as hemorrhaging requiring transfusion or other treatment, the NASEM committee found that the complication rate after an aspiration abortion, ranged from zero to 4.7 percent with most recent studies reporting a rate of 1.3 percent. *Id*. at 61. Similarly, incidences of uterine perforation from aspiration abortions were reported from a range of < 0.1 to 2.3 percent, from older studies, while the majority of more recent studies have found no cases of uterine perforation or note that where perforations occurred most were successfully managed conservatively without the need for additional surgery or hospitalization. *Id*. at 62.

58. COMMENT: One commenter states that although this commenter sympathizes with accessibility issues for women who seek abortions, safety issues far outweigh the need for access. To support this assertion, the commenter states that beyond nine to 10 weeks of gestation, great skill [page=2040] and experience is needed to abort safely; and that although suction curettage is usually uneventful, the risk of uterine perforation and severe, life-threatening hemorrhaging go up with advancing gestational age. As an anecdote, this commenter relates that, two years ago, this commenter witnessed a case in which a young mother would have lost her life had advanced gynecological surgical support not been immediately available.

RESPONSE: The Board agrees that skill and experience are essential attributes for health care providers. The Board further recognizes that competency, standards of care and scope of practice rules remain elements of health care regulation and notes that the proposed rule does change requirements related to standards of care and competency. The Board believes that the proposed rule ensures appropriate protections by defining and regulating post-first-trimester abortions as "special procedures." See also the Response to Comment 57.

59. COMMENT: Commenters do not believe that office settings are safe for abortion procedures after 14 weeks gestation. One commenter states that APCs are not allowed to conduct other medical procedures such as an appendectomy or caesarian section without a physician surgeon's supervision and therefore it would be equally inappropriate for an APC to perform surgical procedures such as an aspiration abortion without similar supervision, putting women, especially women from vulnerable populations, at risk.

RESPONSE: The Board thanks the commenter for sharing the commenter's experience. It is the position of the Board, however, that based on up-to-date clinical and evidence-based research, post-first-trimester abortions proposed to be defined as a "special procedure" can be safely and effectively performed in an office under the safeguards at Rule 4A. In support of this position the Board points to its review of the following: (1) ANSIRH's research on state regulations of facilities providing abortions and its conclusion that there are no benefits to patient safety or patient experience from requiring outpatient procedures to be performed in ASCs instead of physician offices, that these requirements reduce patient access and specifically, that research has failed to find any health benefits from requirements that abortions be performed in an ASCs as opposed to office settings. *State Law Approaches to Facility Regulation of Abortion and Other Office Interventions*, OBS Laws vs TRAP Laws, (ANSIRH, Oakland, C.A.), Feb. 2018, http://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf. *See also* Sarah C. M. Roberts, et al., *Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions*, 319 JAMA 2497 (2018); Nancy F. Berglas, et al., *The Effect of Facility Characteristics on Patient Safety, Patient Experience, and Service Availability for Procedures in Non-Hospital-Affiliated Outpatient Settings: A Systematic Review*, 13 PLoS One (2018). (2) NASEM's research on the safety and quality of abortions in the United States, which found that most abortion procedures can be safely provided in an office-based setting and that minimum facility requirements for a safe procedure are dependent on the level of sedation used. Nat'l Academies of Sciences, Engineering, and Medicine, *supra*, at 10, 26.

It is also the Board's position that removing the "physician only" restriction by repealing Rule 4.2, as it pertains to early aspiration abortions, is scientifically supported and safe. The largest and leading study in patient safety data in California found no clinically significant difference in complication rates between newly trained APCs and physicians, in performing early aspiration abortions. Tracey Weitz, et al., *supra*, at 454. Also see the Response to Comments 36 and 40. *Id.* Also see reference to the NASEM report in the Response to Comment 43. Finally, the Board notes that the comparison between an appendectomy or a caesarian section, which are invasive surgical procedures, and early aspiration abortion, which is a minor procedure, is inapposite. Aspiration abortions are the most common method of first trimester abortion, take only a few minutes to complete and are typically available without anesthesia. Tara C. Jatlaoui, et al., *Abortion Surveillance-United States, 2016*, Morbidity and Mortality Weekly Report, Nov. 29, 2019, at 1, 26, http://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6811a1-H.pdf. Further, unlike an appendectomy or a caesarian section, an aspiration abortion does not require an incision and is an intervention performed through a natural body cavity and, thus, appropriately termed as a "procedure" vs. a surgery. See: ACOG's January 2018 position statement on the "Definition of "procedures" related to Obstetrics and Gynecology," http://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/definition-of-procedures-related-to-obstetrics-and-gynecology.

60. COMMENT: One commenter, who is concerned about patient safety, objects to second trimester abortion procedures taking place outside hospital settings.

RESPONSE: The Board's primary concern, within the context of this rulemaking, is to protect the health, safety, and welfare of the patient who is undergoing an abortion procedure. To that end, the science and evidence-based research consulted for this rulemaking suggest that most abortion procedures can be safely provided in appropriately equipped and staffed office-based settings. Specifically, the NASEM Committee in its research concluded that the minimum facility requirements for a safe abortion procedure depend on the level of sedation used. Nat'l Academies of Sciences, Engineering, and Medicine, *supra*, at

10, 26. For instance, the NASEM committee found that if moderate sedation is used, "the facility should have emergency resuscitation equipment and an emergency transfer plan, as well as equipment to monitor oxygen saturation, health rate, and blood pressure," and for procedures that require deep sedation or general anesthesia, "the facility should be similarly equipped and also have equipment to provide general anesthesia and monitor ventilation." *Id.*

N.J.A.C. 13:35-4A, regulates surgical procedures, special procedures, and anesthesia services in an office. Under the proposed amendments at Rule 4A, first trimester abortions may be performed in appropriately equipped and staffed offices. Post-first-trimester abortions are included within the definition of "special procedure[s]," and will, thus, be subject to the additional policies, procedures, staffing requirements at Rule 4A, all of which are intended to ensure patient safety in the office setting.

61. COMMENT: One commenter states this rulemaking will pose a substantial risk to the health and welfare of women because non-surgeons may not have the capability or training to recognize and address potential complications, including hemorrhages and uterine perforation, which require immediate intervention.

RESPONSE: The Board is governed by its mandate to, above all else, protect the health, safety, and welfare of patients in all medical procedures and services, and in this context, patients who undergo abortion procedures. Contrary to the assertion of the commenter the Board does not believe that the rulemaking will pose a substantial risk to the health and welfare of women by removing the "physician only" restriction as it relates to early aspiration abortion. The Board is proposing to define "early aspiration abortion" as a procedure that terminates a pregnancy through 14 weeks of gestation "utilizing manual or electric suction to empty the uterus" without the use of anesthesia services. In its review of resources, the Board has determined that aspiration abortions are the most common method of first trimester abortion, take only a few minutes to complete and are typically available without anesthesia. Jatlaoui, et al., *Abortion Surveillance--United States*, *supra*. Further, allowing APCs to perform early aspiration abortions, so long as it is within their scope of practice and addressed within their collaborating agreement, does not put at risk the health and welfare of patients undergoing abortions. Studies consulted by the Board have found no clinically significant difference in the rate of complications arising between APCs and physicians. Tracey Weitz, et al., *supra*, at 454. Specifically, with regard to complications, such as hemorrhaging requiring transfusion or other treatment, the NASEM committee found that the complication rate after an aspiration abortion, ranged from zero to 4.7 percent with most recent studies reporting a rate of 1.3 percent. *Id*. at 61. Similarly, incidences of uterine perforation from aspiration abortions were reported from a range of < 0.1 to 2.3 percent from older studies, while the majority of more recent studies have found no cases of uterine perforation or note that where perforations occurred most were successfully managed conservatively without the need for additional surgery or hospitalization. *Id*. at 62.

62. COMMENT: The American Academy of Medical Ethics (AAME), which describes itself as a national group of health care professionals dedicated to the practice of ethical medicine, expresses concern with the proposed rule change. The AAME notes that surgical abortion can be very difficult and that repealing the "physician only" rule would expose women to complications and potential death because the vast majority of non-physicians do not have the requisite training, specifically the training to [page=2041] manage abortion-related complications. Access to abortion, the AAME states, is not worth compromising the health and welfare of women seeking abortion who depend on the BME's health care standards of excellence.

RESPONSE: After a comprehensive review of current evidence-based research, it is the Board's conclusion that removing the "physician only" restriction as it pertains to early aspiration abortion and allowing APCs to perform such procedures is safe. In reaching this conclusion, the Board reviewed the largest and leading study in patient safety data from California. That study found no clinically significant difference in complication rates between newly trained APCs and physicians in performing early aspiration abortions. Tracey Weitz, et al., *Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under A California Legal Waiver*, 103 Am. J. of Pub. Health 454, 454 (2013). See also the Response to Comments 25 and 47. Also see reference to the NASEM report in the Response to Comment 43.

63. COMMENT: One commenter is concerned that removing admitting privilege requirements for physicians who provide abortions will lead to further delay in the transfer of critically ill patients with the potential for greater harm and the risk of death.

RESPONSE: Under the current rulemaking, the Board notes that physicians who perform post-first-trimester abortions, proposed to be defined now as a "special procedure," will still be required to have either hospital, board-approved, or ASC privileging. N.J.A.C. 13:35-4A.6(b)1 requires "a written transfer agreement with a licensed hospital with acute care capabilities, which can be reached within 20 minutes, during all hours in which the procedures will be performed, if the hospital where the practitioner is privileged, cannot be reached within 20 minutes or if the practitioner is privileged by the Board," and paragraph (b)2 requires a "written policy for handling emergency transport" to the hospital where the practitioner holds a privilege, through 9-1-1 calls or "a written agreement with a licensed ambulance service which assures immediate transport of patients experiencing complications to the hospital where the practitioner has established a transfer agreement." The safeguards established within this provision, therefore, ensure that patients do not suffer any risk of delay if transfer to a hospital is required.

64. COMMENT: Commenters argue that allowing APCs to perform abortions will result in more complications for patients. In support of this argument, commenters state that APCs do not have adequate education and training because of their limited medical and surgical exposure For example, one commenter claims that nurses, physician assistants, and midwives have limited training, much of which is obtained part-time over a period of three to five years. Further, this commenter states, prospective patients will not have the option to consider APCs' training and feedback from other patients regarding the APC providers, unlike with physicians, placing these women at a disadvantage. Another commenter states that APCs do not have the training of physicians as to thinking "outside the box" and under pressure.

RESPONSE: With regard to concerns about APC training and the quality of abortion care provided by APCs, see the Response to Comment 36. Additionally, the Board does not agree that patients will not be able to consider APCs training and feedback from other patients regarding APC providers. Patients will be able to discuss APCs' backgrounds with those providers during pre-procedure consultations. Additionally, there is no indication that patients can obtain information from other patients about physicians that they cannot obtain about APCs.

65. COMMENT: One commenter states that allowing abortion procedures by non-medical personnel in an office setting will reduce this surgical procedure to an "office task" less regulated than a tooth extraction.

RESPONSE: The Board disagrees with the commenter's characterization of APCs as "non-medical personnel." It is also the Board's position that lifting the "physician only" restriction for performing early aspiration abortions does not adversely affect the health, welfare, and safety of patients who wish to undergo such procedures. The Board finds the "physician only" rule unnecessary to secure the health and safety of the public in addition to creating barrier to abortion access. APCs are health care providers, who, as research and studies have shown, and as the Board recognizes after drawing on its own expertise, can perform early aspiration abortions safely and effectively. Tracey Weitz, et al., *supra,* at 454.

66. COMMENT: One commenter, in support of the majority of the components of the rulemaking, expresses concerns about abortions up until 14 weeks of pregnancy being carried out in offices. This commenter inquires whether these offices will have access to medications, such as misoprostol, Hemabate, methergine, oxytocin; have access to sterile instruments; be prepared to handle complications; provide adequate pain management and counseling after the procedure; ensure the presence of IV or general anesthesia; and provide post-operative care.

RESPONSE: Pursuant to existing Rule 4A, medical care of comparable complexity and risk to early aspiration abortions and special procedures are currently performed in offices throughout the State as a matter of course. Additionally, abortions through the first 14 weeks of pregnancy are currently performed in office settings by physicians pursuant to existing Rule 4.2. The Board is not aware of any reason that, in the future, office-based practices will not be able to obtain the medications and materials referenced by the commenter or provide patients with necessary anesthesia and post-procedure care and counseling.

67. COMMENT: One commenter inquires who will determine and ensure that APCs are licensed and properly trained to perform early aspiration abortions.

RESPONSE: Pursuant to this rulemaking, APCs are defined as advance practice nurses (APNs) licensed pursuant to N.J.S.A. 45:11-45, physician assistants licensed pursuant to N.J.S.A. 45:9-27.10, or certified nurse midwives (CNMs) and certified midwives (CMs) licensed pursuant to N.J.S.A. 45:10-1. The respective boards licensing each category of clinician will continue to issue licenses to eligible applicants. The respective licensing boards are also charged with determining the scope of practice for each group of clinicians. The Board notes that while the rulemaking lifts the "physician only" restriction and allows APCs to perform early aspiration abortions, it does so only so long as their respective scopes of practice allow it.

68. COMMENT: One commenter states that the risks associated with abortion procedures, such as an increased risk of breast cancer, premature birth rates, and psychological damage, are not being addressed by the Board's rulemaking. In support of this position, the commenter cites to a documentary titled "HUSH" (2015) directed and created by Punam Kumar Gill, who the commenter describes as a pro-choice filmmaker. This commenter also questions whether the Board contemplated requiring providers to counsel patients prior to providing abortion procedures, as required prior to other surgical procedures.

RESPONSE: Abortion is legal medical care in the State of New Jersey and the right to abortion is Constitutionally protected. Legal abortion has a well-documented safety record. The Board has considered many studies, including the NASEM report which, among other things, considers the epidemiologic research evaluating concerns raised by the commenter (http://www.nap.edu/read/24950/chapter/6#151), see the Response to Comment 37. Providers are required to adhere to the standard of care, obtain informed consent and provide relevant, accurate and timely medical information to patients when

performing *all* medical procedures. Therefore, the Board declines to impose an additional, abortion-specific counseling requirement.

69. COMMENT: One commenter suggests that the Board require women to receive counseling before making the decision to have an abortion and also states that there are many resources for women and their partners who wish to keep a baby.

RESPONSE: Providers are required to adhere to the standard of care, obtain informed consent and provide relevant, accurate, and timely medical information to patients when performing *all* medical procedures. Therefore, the Board declines to impose an additional, abortion-specific counseling requirement.

70. COMMENT: Commenters believe that the proposed rules do not address or seek to help women who undergo abortion because of trying circumstances, and that instead of making abortion more accessible the Board should encourage women to put up their children for adoption.

RESPONSE: Individual decisions regarding adoption are outside the scope of the Board's rulemaking and the Board's statutorily proscribed jurisdiction. Rather, the Board has determined to regulate abortions as it would any other legal medical procedure of comparable involvement and [page=2042] risk. The Board declines to change the rule based on the commenters' recommendation.

71. COMMENT: One commenter states that the Board is incorrect in its finding that restricting certain abortion procedures to designated medical facilities is medically unnecessary and "outdated." In support of this argument, the commenter states that the current rule ensures that women have comprehensive care; that most private offices are not adequately supervised; and that U.S. Public Health Community Centers, hospital-affiliated clinics and most non-profit clinics, where comprehensive care is provided, operate with Federal oversight, quality control, and assurances as to good medical practice.

RESPONSE: Pursuant to existing Rule 4A, medical care of comparable complexity and risk to early aspiration abortions and special procedures are currently performed in offices throughout the State as a matter of course. Additionally, abortions through the first 14 weeks of pregnancy are currently performed in office settings by physicians pursuant to existing Rule 4.2. Research reviewed by the Board specific to abortion notes that "more than 95% of induced abortions are provided in outpatient, non-hospital-based settings--in abortion clinics, nonspecialized clinics, or physician offices.< >Abortions have been performed in these settings for more than 45 years," (internal citations omitted) and evaluated 50,311 induced abortions in a retrospective cohort study and found "performance of the abortion in an ambulatory surgical center compared with an office-based setting was not associated with a significant difference in abortion-related morbidities and adverse events." Roberts SCM, Upadhyay UD, Liu G, et al. Association of Facility Type With Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions. *JAMA.* 2018;319(24):2497-2506. doi:10.1001/jama.2018.7675. *See also*http://www.nap.edu/read/24950/chapter/6#151. This Board is the entity charged with regulating providers of office-based health care to ensure public safety and retains all enforcement and disciplinary authority to do so.

72. COMMENT: Commenters believe that the rulemaking will lower the medical standard of care and lead to frequent injuries to patients during abortion procedures.

RESPONSE: The Board emphasizes that it continues to expect providers to meet the applicable standard of care. The medical standard for all procedures comparable to abortion procedures in complexity and risk will remain the same, as the rulemaking treats these procedures in part according to the anesthesia levels required. For instance, early aspiration abortion, proven to be a safe procedure that predominantly does not require moderate to general anesthesia, falls under the definition of "minor procedure" and, therefore, like similar procedures, does not trigger privileging process requirements, patient selection standards, recovery requirements, discharge protocol requirements, and heightened equipment mandates at Rule 4A. Post-first-trimester abortions and those requiring moderate to general anesthesia (neither of which falls within the definition of "early aspiration abortion") would be defined as "special procedures" and, like all special procedures, will be required to adhere to the safeguards and protections pursuant to Rule 4A.

73. COMMENT: One commenter states that common sense dictates that women seeking abortions are safer in a hospital and under the care of a physician. This commenter, therefore, does not agree that advanced practice clinicians should be allowed to perform abortions or that abortions should be allowed to be performed in an office setting.

RESPONSE: The Board notes that proposed N.J.A.C. 13:35-4A.19 will remove the "physician only" bar for early aspiration abortions only, allowing physicians to authorize APCs to perform these procedures, so long as it is within the scope of practice of an APC's collaborating agreement. The Board also notes that the largest study to date, examining patient safety data in California through analysis of 11,487 procedures, confirms and affirms that early aspiration abortions provided by APCs are safe, noting that abortion complications were clinically equivalent between newly-trained APCs and experienced physicians, which supports other evidence from smaller studies. Further, ACOG's committee opinion on abortion education and training recommends expansion of the pool of trained abortion providers to include both family physicians and APCs by integrating first trimester abortion training into APCs' training programs and eliminating the "physician only" bar. ACOG Committee Opinion No. 612: Abortion Training and Education (November 2014), http://pubmed.ncbi.nlm.nih.gov/25437741/.

Based on its thorough review of the research cited within the notice of proposal Summary, the Board also concluded that abortion procedures can be safely provided in an office setting. For example, recent studies reviewed by the Board, such as the research from Advancing New Standards in Reproductive Health (ANSIRH), a collaborative research group at the University of California, concluded that patient safety or patient experience is not compromised when these procedures take place in a physician's office, and that requiring these procedures to be done exclusively in a hospital or ASC reduces patient access to abortion care. The NASEM report also finds that abortion can be safely provided in an office setting and that the need for facility upgrades and equipment mandates depends more on the level of anesthesia or an assessment of other patient-specific risk factors.

74. COMMENT: Commenters believe that APCs do not have the skillset required to perform early aspiration abortions, in contrast to physicians who have many years of experience and training. These commenters believe it would not be safe to remove the "physician only" mandate or to allow APCs to perform early aspiration abortions.

RESPONSE: Based on recent research, science, and evidence-based studies, it is the Board's position that removing the "physician only" restriction for performing early aspiration abortion is safe and does not adversely affect the health, safety, and welfare of the public. In support of its position, the Board points to the largest and leading study of patient safety data in California, which found no clinically significant

difference in complication rates between newly trained APCs and physicians in performing early aspiration abortions. Tracey Weitz, et al., supra, at 454. Also see reference to the NASEM report in the Response to Comment 43.

75. COMMENT: One commenter argues that relying on the studies cited in the rulemaking, which found that there are few complications arising from abortion procedures, to support allowing APCs to perform abortions is misguided because the studies are of physicians performing abortions. This commenter claims that there are no statistics related to what happens when APCs perform abortions.

RESPONSE: The Board notes that contrary to the assertion of the commenter, the Board considered evidence of patient safety in aspiration abortions specifically performed by APCs, relative to comparable care provided by physicians. The Board reviewed the largest and leading study in patient safety data in California, which found no clinically significant difference in complication rates arising from early aspiration abortions performed by trained APCs and physicians. Tracey Weitz, et al., *supra*, at 454. Also see reference to the NASEM report in the Response to Comment 43.

76. COMMENT: One commenter strongly opposed expanding the pool of providers to APCs and states that APCs, despite having technical skills, are minimally trained and since everybody and every procedure is unique, complications that APCs are not equipped to handle can arise. To support this argument, the commenter adds that obstetrician gynecologists (OBGYN) go through four years of medical school and then four years of specialized training in surgery. This intense training and education arm OBGYNs with the skills to save lives by avoiding and managing surgical complications, such as hemorrhages, infections, uterine perforations, damage to the bowel or bladder, thrombotic emboli, and retained fetal tissue. Nurse practitioners and physician assistants can be licensed within six years post-high school, in contrast to the 12 years of school and training required for OBGYNs.

RESPONSE: The Board does not believe that a simple comparison of the total years of training and education between physicians and APCs is dispositive in the context of this rulemaking. The Board has determined through its research that early aspiration abortion is a relatively low-risk procedure, which studies have shown is equally low-risk when performed by APCs. The Board, therefore, has found that the current "physician only" restriction applicable to early aspiration abortion is medically unnecessary. Allowing physicians to authorize APCs to perform aspiration abortions, so long as it is within their scope of practice to do so and addressed in their collaborative agreement, is safe and consistent with ensuring the health, safety, and welfare of the public. See Tracey Weitz, et al., *supra*, at 454; American Public Health Association, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants*, [page=2043] Policy Statement Database (Nov. 1, 2011), http://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants#Anchor%201; ACOG Committee Opinion No. 612: Abortion Training and Education (November 2014), http://pubmed.ncbi.nlm.nih.gov/25437741/.

77. COMMENT: One commenter states that as a registered nurse, the commenter does not believe that the commenter can perform early aspiration abortion without substantial training and safeguards in place.

RESPONSE: Although the rulemaking removes the "physician only" restriction and effectively allows practitioners to authorize APCs to perform early aspiration abortions in the office, the Board is not mandating APCs to perform such procedures. Further, the proposed language clarifies that practitioners can authorize APCs to perform such procedures *as long as it is consistent with their respective scope of*

practice and is addressed within their individual collaborating agreements. The Board also notes that the commenter self-identifies as an RN and further notes that the rulemaking applies to APNs, not RNs.

78. COMMENT: One commenter questions whether APCs, such as midwives, are as able as physicians to handle emotional issues that arise for patients.

RESPONSE: Under current midwifery rules, certified midwives and certified nurse midwives are permitted to provide well-woman care throughout the life cycle, which includes gynecological and primary health care screening; assessment and treatment; and contraceptive services. N.J.A.C. 13:35-2A.13. With proposed N.J.A.C. 13:35-4A.19, the Board is effectively permitting practitioners to authorize APCs to perform early aspiration abortions, so long as it is within an APC's scope of practice and as addressed within their individual collaborating agreements. Although the scope of practice is to be determined by the respective licensing boards of APCs, the Board maintains its position, developed based on its own expertise and through its review of relevant research, that allowing APCs to perform early aspiration abortion is safe and will not adversely affect the health, safety, and welfare of patients undergoing such a procedure. See Tracey Weitz, et al., *supra*, at 454.

79. COMMENT: Two commenters ask whether there will be abortion-related conscience protection for APCs.

RESPONSE: The Board recognizes that when a patient needs abortion care and a provider is unwilling or unable to provide such care, referral may be required to meet the standard of care. The Board also recognizes that health care personnel, including APCs may, under certain Federal or State laws not administered by the Board and not at issue in this rulemaking, refuse to provide abortion care.

80. COMMENT: One commenter states that APCs are already performing aspiration abortions under supervision or in collaboration with a physician and asks whether the supervision requirement of a physician will still exist or whether APCs will now be allowed to perform such procedures independently. The commenter also inquires whether APCs will be required to have hospital privileges or have the opportunity to speak with a physician if complications arise or in general. Finally, this commenter states that having a physician supervise the APCs is safer, although the commenter has full confidence in APCs.

RESPONSE: The Board's rulemaking does not address or alter collaborating, supervisory, or privileging rules for APCs. All licensed health care professionals are expected to meet standards of care including and especially when complications arise. To the extent that consultation with or referral to another provider is required to meet the standard of care, such obligation is unaltered by the Board's rulemaking.

81. COMMENT: Commenters state that removing the current hospital privileges requirement for physicians performing abortions is not safe because of the possibility of emergencies arising during such procedures.

RESPONSE: A provider's privileging status is not a prerequisite to treatment of a patient in a hospital an emergency. Abortion-specific privileging requirements were invalidated by the United States Supreme Court in *Whole Woman's Health v. Hellerstedt*. Here the Board replaces prior rules in favor of an integrated approach that includes abortion care within health care regulation of general applicability. Providers performing abortions other than early aspiration abortions will be required to have admitting privileges at a hospital or ASC pursuant to N.J.A.C. 13:35-4A.6. The Board proposes to amend N.J.A.C. 13:35-4A.6(a), which currently requires practitioners to obtain either hospital privileges or alternative

privileges from the Board to perform surgery or special procedures, to recognize privileging by ASCs as well, but the Board is not removing the privileging requirement. The Board notes that ASC privileging is governed by the New Jersey Department of Health (DOH) and that DOH's rules are comprehensive. For instance, the DOH rule at N.J.A.C. 8:43A-7.3 requires a medical director to participate in "the review of credentials and delineation of privileges of medical staff members, and assign ... duties based upon education, training, competencies, and job descriptions." Additionally, N.J.A.C. 8:43A-12.3 requires ASCs to have a board-certified physician director responsible for surgical services, and pursuant to N.J.A.C. 8:43A-12.4(b), an ASC must also have a board-certified physician director of anesthesia services who participates in the credentialing process and delineation of privileges. Consequently, the Board is proposing to add a definition of ASC pursuant to N.J.A.C. 13:35-4A.3, and the definition of "privilege" will be amended to include authorization granted by an ASC licensed by DOH.

82. COMMENT: One commenter inquires which administrative agency will be responsible for regulating offices to ensure the health and safety of abortion patients.

RESPONSE: Special procedures and minor procedures in offices must be performed pursuant to the terms of N.J.A.C. 13:35-4A. Post-first-trimester abortion procedures, proposed to be defined as "special procedures," will be similarly regulated by the Board to ensure the health, safety, and welfare of the public. Regardless of where an individual practices, the State Board of Medical Examiners is responsible for regulating the conduct of physicians and physician assistants; the Midwifery Liaison Committee, which falls under the supervision of the State Board of Medical Examiners, is responsible for the regulation of midwives; and the Board of Nursing is responsible for the regulation of APNs. The Department of Health (DOH) will continue to regulate DOH-licensed ambulatory surgery centers (ASC).

83. COMMENT: One commenter is concerned for crisis pregnancies and also believes that the rulemaking would result in more frequent injuries to women. The commenter states that current practices continue to result in frequent injury to women.

RESPONSE: The Board's rulemaking is intended to remove medically unnecessary barriers to care that prevent patients from receiving care they need. In this way, the Board seeks to increase patients' options, including when they face what the commenter refers to as "crisis pregnancies." As with all other medical procedures, the determination whether to proceed with an abortion is one made by a patient in consultation with a medical provider, and in a manner that weighs many factors including the benefit to the patient and the risks involved in the procedure. The Board notes, however, that while governmental requirements are appropriate to protect public health and safety in some circumstances, the Board has determined that the rule as adopted reflects the most appropriate means of protecting public health and safety in the context of abortions. Additionally, abortion providers who perform post-first-trimester abortions are required to follow the guidelines at N.J.A.C. 13:35-4A.6(c), which specifies that only patients who meet the physical health requirements that qualify them for the American Society of Anesthesiology (ASA) Level I or II classification may undergo surgery or a special procedure in an office.

84. COMMENT: One commenter states that the rulemaking furthers the New Jersey government's and Legislature's agenda to reduce the number of African Americans. The commenter states that in Michigan, while 13 percent of the population are black women, this population has a 50 percent rate of abortion, and that former president Richard Nixon was recorded in the White House Tapes making a similar assertion.

RESPONSE: Abortion is a legal medical procedure and the individual right to an abortion is Constitutionally protected. Notably, racial disparities in rates of unplanned pregnancy and the related rate of demand for abortion reflect systemic inequities more appropriately addressed by systemic solutions that advance health equity and bodily autonomy through meaningful access to the full range of reproductive health care, rather than by abortion restrictions.

85. COMMENT: Commenters state that because some minority populations end pregnancies at disproportionately higher rates, the State should not advance access to abortion. To support this position, one commenter references an article discussing racial disparities in terms of [page=2044] years of potential life lost (by fetuses) attributable to abortion (Studnicki, J. MacKinnon, S. J., and Fischer, J.W. (2016) Induced Abortion, Mortality, and the Conduct of Science. *Open Journal of Preventive Medicine*, 6, 170-177. http://dx.doi.org/10.4236/ojpm.2016.66016)

RESPONSE: The Board recognizes abortion is an essential element of comprehensive reproductive health care. All persons, regardless of race or other demographic variables, have the right to carry a pregnancy to term or to terminate a pregnancy. To that end, the Board proposes an updated, integrated and evidence-based regulatory approach designed to simultaneously ensure public safety and access to the full range of reproductive health care options.

86. COMMENT: One commenter believes the Board's rulemaking will encourage more women to have abortions.

RESPONSE: The Board rulemaking neither encourages nor discourages abortion. The Board recognizes abortion is an essential element of comprehensive reproductive health care and here proposes an updated, integrated, and evidence-based regulatory approach to that end.

87. COMMENT: One commenter states that the rulemaking does not discuss or reflect its full impact on public health.

RESPONSE: The Board considered the impact of the rulemaking on public health. The Board recognizes that unnecessary rules limiting the health care provider supply harm public health. A robust supply of trained, licensed health care providers advances patient access to timely care and improves public health. As noted in the rulemaking, "[a]bortion is an essential element of reproductive healthcare" and "it is critical to the public health interests of the United States that all women have meaningful access to reproductive health services, including abortion." Amici Curiae Brief of Public Health Deans, et al. in Support of Petitioners at 3, *Whole Woman's Health v. Hellerstedt*, 136 *S.Ct*. 2292 (No. 15-274). The proposed repeal of Rule 4.2 will have a positive impact on individuals seeking abortions because it clears the path for expanded access to a broader pool of abortion providers and removes unnecessary barriers to abortion care, while retaining the elements of general health care regulation connected to public safety.

88. COMMENT: One commenter suggests that instead of allowing less-experienced health care professionals to perform abortions and allowing abortions in an unsafe setting, the Board should take action to encourage women to seek help with preventive measures, such as birth control, to avoid unwanted pregnancies.

RESPONSE: The Board proposal enables an increased number of trained health care professionals to provide abortion care based on careful evaluation of relevant research. Although the Board recognizes that

access to birth control is a widely acknowledged public health imperative, it is outside the scope of this rulemaking.

89. COMMENT: One commenter suggests that the Board support family planning initiatives, including using contraceptives, instead of seeking to expand access to abortion.

RESPONSE: The purpose of the rulemaking is to remove barriers to access in the form of Board regulation of abortion procedures, which barriers the Board has determined are medically unnecessary. The suggestion from the commenter regarding the Board's support of family planning initiatives, including using contraceptives, is outside the scope of this rulemaking.

90. COMMENT: Commenters note that within the rulemaking summary, it is incorrectly stated that the Board of Medical Examiners currently licenses 10,640 advanced practice nurses, since it is the Board of Nursing (BON) that licenses APNs. One commenter also adds that the Board does not have any authority to establish the scope of practice for APNs and requests that there be joint jurisdictional authority if the rule is enacted.

RESPONSE: The Board clarifies that proposed N.J.A.C. 13:35-4A.19 would allow physicians to authorize APNs to perform early aspiration abortions consistent with APNs' scope of practice and as addressed within each physician and APN's collaborative agreement. The Board is neither establishing nor dictating the scope of practice of APNs and recognizes that BON has the sole authority to do so. For the purpose of this rulemaking, therefore, there is no need for joint jurisdictional authority. The Board also acknowledges that it is BON that licenses APNs and that the notice of proposal Summary mistakenly states that the Board has this authority. The Board stands ready to collaborate in any way the BON may find useful.

91. COMMENT: One commenter requests clarity and transparency for physicians and the public as to the chain of custody of aborted fetal tissue.

RESPONSE: Existing rules already provide for proper handling of fetal tissue. N.J.A.C. 13:35-4.2(h) states that "[t]he physician shall make suitable arrangements to insure that all tissues removed shall be properly disposed of by submission to a qualified physician for pathologic analysis or by incineration or by delivery to a person/entity licensed to make biologic and/or tissue disposals in accordance with law." Despite the proposed repeal of Rule 4.2, abortion service providers, like all other medical service providers, are still subject to N.J.S.A. 13:1E-48.4 and the Department of Environment Protection's corollary regulation, N.J.A.C. 7:26-3A, concerning regulated medical waste. Additionally, N.J.A.C. 13:35-4A.4(a)4 will continue to require providers of surgery and special procedures to have written policies and procedures concerning lawful disposal of medical waste. The Board has, therefore, determined that no change to the rule are necessary.

92. COMMENT: One commenter claims that, per Federal regulations, the Centers for Disease Control and Prevention's International Classification of Diseases 10 (ICD 10) and billing Current Procedural Terminology (CPT) codes, list a first-trimester non-medication abortion as a "minor surgical procedure" for which an operative report is required. This commenter questions whether the proposed amendment to deem early aspiration abortion and later term abortions as "minor procedures" and "special procedures," respectively, will conflict with current billing practices.

RESPONSE: The Board notes that billing terminology often does not coincide with terminology used in the medical profession. The Board declines to revise its position on the use of the term "procedure" but encourages communication and feedback from providers in the event of billing conflicts.

Summary of Agency-Initiated Change Upon Adoption:

The Board has changed the reference to the "Department of Health and Senior Services" within the definition of "office," at N.J.A.C. 13:35-4A.3, by deleting "and Senior Services" to reflect the current and accurate name of the agency.

Federal Standards Statement

A Federal standards analysis is not required because there are no Federal laws or standards applicable to the rulemaking.

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks, ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 4. SURGERY

13:35-4.2 (Reserved)

SUBCHAPTER 4A. SURGERY, SPECIAL PROCEDURES, AND ANESTHESIA SERVICES PERFORMED IN AN OFFICE SETTING

13:35-4A.1 Purpose

The rules in this subchapter are designed to promote the health, safety, and welfare of the members of the general public who undergo surgery or special procedures (other than minor procedures) and receive anesthesia services in an office, ensuring that such services are offered in a manner consistent with the standard of care.

13:35-4A.2 Scope

(a) This subchapter establishes policies and procedures and staffing and equipment requirements for practitioners and physicians who perform surgery or special procedures (other than minor procedures) or administer anesthesia services in an office and represent the standard of care in a surgical practice.

(b) For the purposes of this subchapter, the standards set forth at N.J.A.C. 13:35-4A.6 do not apply to those performing non-invasive special procedures, such as non-invasive radiologic procedures. However, the standards set forth at N.J.A.C. 13:35-4A.7 do apply to the anesthesia [page=2045] services provided in connection with all special procedures, whether invasive or non-invasive.

(c) For the purposes of this subchapter, the *[established]* standards ***in this chapter*** shall not be applicable to the performance of medication abortions, whether as a result of prescriptions issued by physicians or advanced practice clinicians.

13:35-4A.3 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

. . .

"Advanced practice clinician" or "APC" means an advanced practice nurse licensed pursuant to N.J.S.A. 45:11-45, a physician assistant licensed pursuant to N.J.S.A 45:9-27.10, or certified nurse midwives (CNMs) and certified midwives (CMs) licensed pursuant to N.J.S.A. 45:10-1.

"Ambulatory surgery center" means a facility licensed by the New Jersey Department of Health pursuant to N.J.S.A. 26:2H-12 and subject to N.J.A.C. 8:43A.

"Anesthesia services" means administration of any anesthetic agent with the purpose of creating moderate sedation, regional anesthesia, or general anesthesia. For the purposes of this subchapter, the administration of topical or local anesthesia, minor conduction blocks, pain management or pain medication shall not be deemed to be anesthesia services.

. . .

"Anesthetic agent" means any drug or combination of drugs administered with the purpose of creating moderate sedation, regional anesthesia, or general anesthesia.

. . .

"Certified registered nurse anesthetist" (CRNA) means a registered professional nurse who is licensed in this State as an advanced practice nurse specializing in anesthesia services and who holds current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA).

"Collaborating agreement" means a written document entered into by an APC and a physician, to include joint protocols for APNs, delegation agreements for PAs, or clinical guidelines for CNMs and CMs.

"Complications" means an untoward event occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia services which was performed in an office including, but not limited to, any of the following events: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, wound infections requiring intravenous antibiotic treatment or hospitalization, uterine perforation or injury to another organ, or unintended return to an operating room or hospitalization, death or temporary or permanent loss of function not considered to be a likely or usual outcome of the procedure.

"Early aspiration abortion" means a procedure that terminates a pregnancy in the first trimester of pregnancy (defined as up to *[12 completed weeks gestation, as confirmed by the patient, or up to]* 14 completed weeks as calculated *[from the last menstrual period and/or by ultrasound]* ***by an estimate of gestational age that utilizes the last menstrual period, ultrasound, and/or physical examination, as appropriate, to the standard of care***) utilizing manual or electric suction to empty the uterus *[and that does not involve the use of anesthesia services]*.

. . .

"Health care personnel" means any office staff member who is licensed by a professional or health care occupational licensing board such as an advanced practice nurse, professional registered nurse, licensed practical nurse, certified nurse midwife, certified midwife, or physician assistant.

. . .

"Minor conduction block" means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, local infiltration or local nerve block), or the block of a nerve by direct pressure or refrigeration. Minor conduction blocks include, but are not limited to, retrobulbar blocks, peribulbar blocks, pudendal blocks, digital blocks, metacarpal blocks, ankle blocks, and paracervical blocks. "Minor conduction block" does not include regional anesthesia that affects larger areas of the body, such as brachial plexus anesthesia or spinal anesthesia.

"Minor procedure" means an intervention that can safely and comfortably be performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intra-operative tranquilization and where the likelihood of complications requiring hospitalization is remote. Minor procedure specifically excludes all procedures performed utilizing anesthesia services as defined in this section. Minor procedure also specifically excludes procedures which may be performed under local anesthesia, but which involve extensive manipulation or removal of tissue such as liposuction or lipo-injection, breast augmentation or reduction, and removal of breast implants. Minor procedure includes the excision of moles, warts, cysts, lipomas, skin biopsies, the repair of simple lacerations, or other procedures limited to the skin and subcutaneous tissue. Additional examples of minor procedures include closed reduction of a fracture, the incision and drainage of abscesses, certain simple ophthalmologic procedures, such as treatment of chalazions and non-invasive ophthalmologic laser procedures performed with topical anesthesia, limited endoscopies such as flexible sigmoidoscopies, anoscopies, proctoscopies, arthrocenteses, thoracenteses, paracenteses, and early aspiration abortions. Minor procedures shall not include any procedure identified as "major surgery" within the meaning of N.J.A.C. 13:35-4.1.

"Moderate sedation" means *[the administration of a drug or drugs in order to induce that state of consciousness in a patient that allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function, and the ability to respond purposefully to verbal command or to tactile stimulation, if verbal response is not possible as, for example, in the case of a small child or deaf person.]* ***a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone, or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is "usually maintained."*** Moderate sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization, such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. Moderate sedation shall be synonymous with the term "sedation/analgesia" as used by the American Society of Anesthesiologists.

. . .

"Office" means a location at which medical, surgical ***,*** or podiatric services are rendered *[that]* ***and which*** contains *[no more than one room or suite of rooms in which surgery or special procedures are performed that]* ***only one operating room and which*** is ***not*** subject to the jurisdiction and licensure requirements of the New Jersey State Department of Health *[as a licensed ambulatory surgery

center]*. *["Office" includes, but is not limited to, registered surgical practices and those sites that are not equipped for the performance of surgery, but at which special procedures may be performed.]*

. . .

"Physical status classification" means a description of a patient used in determining if an office surgery or special procedure is appropriate. The American Society of Anesthesiologists enumerates classifications: I--Normal healthy patient; II--A patient with mild systemic disease; III--A patient with severe systemic disease limiting activity but not incapacitating; IV-- A patient with incapacitating systemic disease that is a constant threat to life; and V--Moribund patients not expected to live 24 hours with or without operation.

. . .

"Privileges" means the authorization granted to a practitioner by a hospital licensed in the jurisdiction in which it is located to provide specified services, or an ambulatory surgery center licensed by the Department of Health or alternatively by the Board pursuant to N.J.A.C. 13:35-4A.12, such as surgery or special procedures or the administration or the supervision of administration of one or more types of anesthetic agents.

[page=2046] . . .

"Special procedure" means patient care that requires anesthesia services because it involves entering the body with instruments in a potentially painful manner, or requires the patient to be immobile; for a diagnostic or therapeutic procedure. Examples of special procedures include diagnostic or therapeutic endoscopy or bronchoscopy performed utilizing moderate sedation or general anesthesia; invasive radiologic procedures performed utilizing moderate sedation, pediatric magnetic resonance imaging performed utilizing moderate sedation, manipulation under anesthesia (MUA), or abortions, other than early aspiration abortions. The term special procedure does not include a procedure which only requires medication to reduce anxiety such as oral benzodiazepine, unless the dose given is intended to provide moderate sedation.

. . .

"Surgery" means a manual or operative procedure, including the use of lasers, performed upon the body for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering. Surgery includes, but is not limited to: incision in tissue or an organ; suture or other repair of tissue or an organ; a closed or open reduction of a fracture.

"Surgical practice" means a structure or suite of rooms that has the following characteristics:

1. Has no more than one room dedicated for use as an operating room that is specifically equipped to perform surgery, and is designed and constructed to accommodate invasive diagnostic and surgical procedures;

2. Has one or more post-anesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and is established by a physician professional association surgical practice, or other professional practice form specified by the State Board of Medical

Examiners pursuant to N.J.A.C. 13:35-6.1(f) solely for the physician's, association's or other professional entity's private medical practice.

. . .

13:35-4A.4 Policies and procedures requirements

(a) Practitioners who perform surgery or special procedures (other than minor procedures), and physicians who administer or supervise the administration or monitoring of anesthesia services in an office shall establish written policies and procedures concerning the following:

1.-10. (No change.)

(b) The written policies and procedures shall also contain the identity of the specific practitioners within the office who are responsible for ensuring that:

1. (No change.)

2. All equipment and instruments utilized in the performance of surgery or special procedures are maintained in proper working order and in accordance with such sterilization techniques as are required for safe medical practice;

3.-5. (No change.)

(c)-(d) (No change.)

13:35-4A.5 Duty to report incidents related to surgery, special procedures, or anesthesia in an office

Any incident related to surgery, special procedures, or the administration of anesthesia services within the office that results in a patient death, transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours, or a complication, shall be reported to the Executive Director of the Board within seven days, in writing, and on such forms as shall be required by the Board. Such reports shall be investigated by the Board and will be deemed confidential pursuant to N.J.S.A. 45:1-36.

13:35-4A.6 Standards for performing surgery and special procedures in an office; privileges necessary; pre-procedure counseling; patient records; recovery and discharge

(a) A practitioner who performs surgery or special procedures (other than minor procedures) in an office shall be privileged to perform that surgery or special procedure by a hospital or an ambulatory surgery center. If a practitioner is not so privileged, but wishes to perform surgery or special procedures in an office, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.

(b) Before any practitioner may perform surgery or special procedures (other than minor procedures), the practitioner shall have:

1.-2. (No change.)

(c) A practitioner who performs surgery or special procedures (other than minor procedures) in an office shall provide pre-procedure counseling and preparation as follows:

1. The practitioner shall appropriately assess, or review a referring physician's * **or an advanced practice clinician's*** assessment of, the physical condition of the patient on whom surgery or a special procedure is to be performed. The practitioner shall refer a patient who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway, or neurological problems; substance abusers) to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility for the performance of the surgery or the special procedure. Only patients with an American Society of Anesthesiologists (ASA) physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II, or III are appropriate candidates for moderate sedation.

2. A history and physical examination shall be performed within the 30 days preceding the proposed surgery either by the practitioner performing the surgery or special procedure (as appropriate to that practitioner's scope of practice) or by another physician or an advanced practice clinician. Necessary laboratory tests, as guided by the patient's underlying medical condition, shall be conducted within seven days preceding the proposed surgery;

3.-6. (No change.)

(d) A practitioner who performs surgery or special procedures (other than minor procedures) in an office shall ensure the following during recovery and prior to discharge:

1.-4. (No change.)

(e) A practitioner who performs surgery or special procedures (other than minor procedures) in an office shall prepare a patient record which shall include the following:

1.-6. (No change.)

(f) No practitioner who performs surgery or special procedures (other than minor procedures) in an office shall:

1.-2. (No change.)

13:35-4A.7 Standards for administering or supervising the administration of anesthesia services in an office; pre-anesthesia counseling; patient monitoring; recovery; patient record; discharge of patient

(a) (No change.)

(b) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall provide pre-anesthesia counseling and preparation as follows:

1. Any patient to whom anesthesia services are to be provided shall be appropriately screened by the individual administering anesthesia services. Patients who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway, or neurological problems; substance abusers) shall be referred to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility. Only patients with an ASA physical status classification of I or II are appropriate candidates for

an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II, or III are appropriate candidates for moderate sedation.

2.-9. (No change.)

(c) A physician who administers or supervises the administration or monitoring of any anesthesia services (general anesthesia, regional anesthesia, or moderate sedation) in an office shall ensure that monitoring is provided as follows when clinically feasible for the patient:

1.-5. (No change.)

(d)-(i) (No change.)

13:35-4A.8 Performance of general anesthesia; authorized personnel

(a) (No change.)

[page=2047] (b) The administration and monitoring of general anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or special procedure. This subsection shall not be construed to preclude the conversion of moderate sedation to general anesthesia in an emergency to protect the health of the patient, even if there is no physician present who would be qualified to administer and monitor general anesthesia pursuant to (a)1 above.

(c) When the administration and monitoring of general anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency without concurrent responsibilities to administer anesthesia or perform surgery or special procedures, other than minor procedures.

(d) (No change.)

13:35-4A.9 Administration of regional anesthesia; authorized personnel

(a)-(b) (No change.)

(c) When the administration and monitoring of regional anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency, without concurrent responsibilities to administer anesthesia or perform surgery or special procedures, other than minor procedures.

(d) (No change.)

13:35-4A.10 Administration of moderate sedation; authorized personnel

(a) Moderate sedation shall be administered in an office only by the following individuals:

1. A practitioner privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide moderate sedation and who, during every consecutive three-year period beginning July 1, 2004, completes at least eight Category I or II hours of continuing medical education in any anesthesia services, including moderate sedation exclusively, or in anesthesia as it relates to the physician's field of practice, which

either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association;

2. (No change.)

3. A registered professional nurse or physician assistant, who is trained and has experience in the use and monitoring of anesthetic agents, at the specific direction of a physician qualified under (a)1 above, but only for the purpose of administering through an established intravenous line, a specifically prescribed supplemental dose of moderate sedation that was selected and initially administered by the physician who remains continuously present in the procedure room. "Continuously present in the procedure room" does not require that a practitioner remain in the procedure room in violation of human exposure safety standards regularly employed during radiological procedures.

(b) A patient under moderate sedation shall be monitored in an office by a physician, CRNA, or a registered professional nurse or physician assistant who has training and experience in the use of monitoring devices, under the supervision of a physician eligible under (a)1 above, to administer moderate sedation.

(c) The monitoring of a patient under moderate sedation shall be provided by an individual who meets the requirements of (b) above and who is at all times present and who is not the practitioner who is performing the surgery or special procedure.

(d) When the administration and monitoring of moderate sedation is being performed by a CRNA, or when the monitoring is being performed by a registered professional nurse or physician assistant, the supervising physician shall be physically present, but may be concurrently responsible for patient care.

(e) An advanced cardiac life support-trained physician, registered nurse, or physician assistant shall be present at all times when a patient is receiving or recovering from the administration of moderate sedation.

13:35-4A.11 Administration of minor conduction blocks; authorized personnel

(a) Minor conduction blocks (with the exception of retrobulbar blocks) shall be administered in an office for surgery or special procedures only by the following individuals:

1.-2. (No change.)

3. An advanced practice clinician who has training and experience in the administration of minor conduction blocks.

(b) Retrobulbar blocks shall be administered in the office only by a physician privileged by a hospital, licensed ambulatory surgery center, or by the Board pursuant to N.J.A.C. 13:35-4A.12.

13:35-4A.12 Alternative privileging procedure

(a) A practitioner who seeks to provide or supervise the administration and monitoring of general or regional anesthesia, as well as moderate sedation, in an office, but does not hold privileges at a licensed hospital or ambulatory surgery center to do so, shall submit, to the Board, an application for these privileges. To be eligible to apply for these privileges, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1.-3. (No change.)

(b) A practitioner who seeks to administer or supervise the administration and monitoring of only moderate sedation in an office, but does not currently hold clinical privileges at a licensed hospital or ambulatory surgery center to do so, shall submit, to the Board, an application for this privilege. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1. Demonstration of clinical experience, through an attestation as to the number of procedures for which moderate sedation was provided by the applicant in the last two years for all age groups within the applicant's practice of patients for which privileges are requested, except age groups as are specifically excluded from the applicant's practice;

2. Any one of the following:

i. (No change.)

ii. Current certification in Critical Care Medicine or Emergency Medicine by a specialty board or certifying entity recognized by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA) or any other certification entity the applicant demonstrates has standards of comparable rigor; or

iii. Satisfactory evidence that the applicant is advanced cardiac life support trained with updated training from a recognized accrediting organization and either:

(1) (No change.)

(2) A course in moderate sedation offered by a licensed hospital or for continuing medical education credits; and

3. Submission of a list of all patients who have experienced complications relating to the applicant's provision of moderate sedation in an office setting or licensed ambulatory care facility setting and their resulting outcomes. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log.

(c) A practitioner who seeks to perform surgery (other than minor surgery) or special procedures in an office, but does not hold privileges at a licensed hospital or ambulatory surgery center to perform these procedures shall submit, to the Board, an application for these privileges, including a completed privilege request form appropriate to the privileges requested. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1.-3. (No change.)

(d) A practitioner who seeks to utilize laser surgery techniques in an office, but does not hold privileges at a licensed hospital or an ambulatory surgery center to do so, shall submit, to the Board, an application, which shall include:

1.-2. (No change.)

(e)-(h) (No change.)

[page=2048] 13:35-4A.19 Performance of minor procedures by advanced practice clinicians

Nothing in this subchapter shall be construed to preclude practitioners from authorizing advanced practice clinicians to perform minor procedures in the office consistent with their respective scopes of practice and as addressed within their individual collaborating agreements.