By Senator Flores

	39-00727A-20 20201764
1	A bill to be entitled
2	An act relating to childbirth; amending s. 382.008,
3	F.S.; requiring a certificate for fetal death to
4	include certain information if the death occurred in
5	association with a planned out-of-hospital birth;
6	amending s. 382.013, F.S.; requiring a certificate of
7	live birth to list the intended place of birth;
8	requiring the certificate to list certain information
9	if the mother or newborn was transferred to a
10	hospital, an intensive care unit, or a similar
11	facility during certain times; amending s. 456.0495,
12	F.S.; revising the definition of the term "adverse
13	incident"; requiring certain health care practitioners
14	to submit adverse incident reports to the Department
15	of Health within a specified timeframe under certain
16	circumstances; requiring the department to investigate
17	adverse incident reports involving unlicensed
18	individuals and take appropriate action; creating a
19	review panel within the department, in consultation
20	with certain regulatory boards; providing for the
21	membership, meetings, and duties of the panel;
22	requiring the panel to submit annual reports to the
23	department, the Board of Medicine, the Board of
24	Osteopathic Medicine, the Board of Nursing, and the
25	Council of Licensed Midwifery by a specified date;
26	requiring the department to collect and analyze
27	certain data relating to adverse incidents in planned
28	out-of-hospital births; requiring the department to
29	submit annual reports on its findings and

Page 1 of 13

	39-00727A-20 20201764
30	recommendations to the Governor and the Legislature by
31	a specified date and publish the report on its
32	website; requiring the department to deidentify
33	information in such report; creating s. 456.0496,
34	F.S.; providing continuing education requirements for
35	and duties of licensed health care practitioners
36	providing out-of-hospital births; requiring the
37	department to adopt rules for such education
38	requirements; requiring a patient informed consent
39	form for out-of-hospital births to include specified
40	information; providing for violations and penalties;
41	providing grounds for disciplinary action; providing
42	an effective date.
43	
44	Be It Enacted by the Legislature of the State of Florida:
45	
46	Section 1. Subsection (1) of section 382.008, Florida
47	Statutes, is amended to read:
48	382.008 Death, fetal death, and nonviable birth
49	registration
50	(1) A certificate for each death and fetal death which
51	occurs in this state shall be filed electronically on the
52	department electronic death registration system or on a form
53	prescribed by the department with the department or local
54	registrar of the district in which the death occurred within 5
55	days after such death and prior to final disposition, and shall
56	be registered by the department if it has been completed and
57	filed in accordance with this chapter or adopted rules. The
58	certificate shall include the decedent's social security number,
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Page 2 of 13

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SB 1764

	39-00727A-20 20201764
59	if available. In addition, each certificate of death or fetal
60	death:
61	(a) If requested by the informant, shall include aliases or
62	"also known as" (AKA) names of a decedent in addition to the
63	decedent's name of record. Aliases shall be entered on the face
64	of the death certificate in the space provided for name if there
65	is sufficient space;
66	(b) If the place of death is unknown, shall be registered
67	in the registration district in which the dead body or fetus is
68	found within 5 days after such occurrence; and
69	(c) If death occurs in a moving conveyance, shall be
70	registered in the registration district in which the dead body
71	was first removed from such conveyance; and
72	(d) If the fetal death occurred in association with a
73	planned out-of-hospital birth, including a fetal death that
74	occurs out-of-hospital or during a transfer or admission to a
75	hospital, an intensive care unit, or a similar facility, shall
76	include the name, title, and professional license number of each
77	physician, certified nurse midwife, or midwife who treated the
78	mother or fetus during the pregnancy, labor, or delivery, or
79	immediately thereafter. If an individual who treated the mother
80	or fetus is not appropriately licensed in this state but
81	represented himself or herself as such, the certificate of fetal
82	death must also include the name of the unlicensed individual
83	and any title or professional license number the individual used
84	to represent himself or herself as appropriately licensed in
85	this state, with a clear notation that the individual is not
86	appropriately licensed as such.
87	Section 2. Subsection (6) is added to section 382.013,

Page 3 of 13

39-00727A-20

88 Florida Statutes, to read: 89 382.013 Birth registration.-A certificate for each live birth that occurs in this state shall be filed within 5 days 90 91 after such birth with the local registrar of the district in 92 which the birth occurred and shall be registered by the local registrar if the certificate has been completed and filed in 93 94 accordance with this chapter and adopted rules. The information 95 regarding registered births shall be used for comparison with 96 information in the state case registry, as defined in chapter 97 61. 98 (6) INTENDED PLACE OF BIRTH.-A certificate of live birth 99 must include the intended place of birth. If the mother or newborn was transferred to a hospital, an intensive care unit, 100 101 or a similar facility at any point during labor or delivery, or within 72 hours of delivery, the certificate must also include 102 103 the name and address of the transferring location and the name, 104 title, and professional license number of each physician, 105 certified nurse midwife, or midwife who treated the mother or 106 newborn during the pregnancy, labor, or delivery, or immediately 107 thereafter. If an individual who treated the mother or fetus 108 prior to such transfer is not appropriately licensed in this 109 state but represented himself or herself as such, the 110 certificate of live birth must also include the name of the unlicensed individual and any title or professional license 111 112 number the individual used to represent himself or herself as 113 appropriately licensed in this state, with a clear notation that 114 the individual is not appropriately licensed as such. Section 3. Section 456.0495, Florida Statutes, is amended 115 116 to read:

Page 4 of 13

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SB 1764

20201764

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39-00727A-20
                                                              20201764
117
          456.0495 Reporting adverse incidents occurring in planned
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     out-of-hospital births.-
          (1) For purposes of this section, the term "adverse
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120
     incident" means an event over which a physician licensed under
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     chapter 458 or chapter 459, a nurse midwife certified under part
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     I of chapter 464, or a midwife licensed under chapter 467 could
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     exercise control and which is associated with an attempted or
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     completed planned out-of-hospital birth, and results in one or
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     more of the following injuries or conditions:
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          (a) A maternal death that occurs during delivery or within
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     42 days after delivery;
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          (b) The transfer of a maternal patient to a hospital
129
     intensive care unit;
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           (c) A maternal patient experiencing hemorrhagic shock or
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     requiring a transfusion of more than 4 units of blood or blood
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     products;
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          (d) A fetal or newborn death, including a stillbirth,
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     associated with an obstetrical delivery;
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           (e) A transfer of a newborn to a neonatal intensive care
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     unit due to a traumatic physical or neurological birth injury,
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     including any degree of a brachial plexus injury;
138
           (f) A transfer of a newborn to a neonatal intensive care
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     unit within the first 72 hours after birth if the newborn
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     remains in such unit for more than 72 hours; or
          (g) Any transfer of a maternal patient or newborn from an
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     out-of-hospital birth setting to a hospital during the prenatal,
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     intrapartal, or postpartal period, as those periods are defined
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     in s. 467.003, that results in fetal or maternal morbidity or
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     mortality; or
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Page 5 of 13

170

20201764 39-00727A-20 146 (h) (q) Any other injury as determined by department rule. 147 (2) Beginning July 1, 2018, A physician licensed under chapter 458 or chapter 459, a nurse midwife certified under part 148 149 I of chapter 464, or a midwife licensed under chapter 467 who 150 performs an attempted or completed planned out-of-hospital birth 151 must report an adverse incident, along with a medical summary of 152 events, to the department within 15 days after the adverse 153 incident occurs. A health care practitioner required to report 154 adverse incidents under this section who is aware of an adverse 155 incident related to an out-of-hospital birth attempted or 156 completed by an individual who was not appropriately licensed in 157 this state but who represented himself or herself as licensed must report such adverse incident, including all related 158 159 information of which the health care practitioner has knowledge, to the department within 15 days after becoming aware of such 160 161 adverse incident. 162 (3) The department shall review each incident report and 163 determine whether the incident involves conduct by a health care 164 practitioner which is subject to disciplinary action under s. 165 456.073. Disciplinary action, if any, must be taken by the 166 appropriate regulatory board or by the department if no such 167 board exists. If the department receives an adverse incident report involving conduct by an unlicensed individual, the 168 169 department shall investigate the individual for unlicensed

171 (4) A review panel is created within the department, in
 172 consultation with the Board of Medicine, the Board of
 173 Osteopathic Medicine, the Board of Nursing, and the Council of
 174 Licensed Midwifery, to review reported adverse incidents

activity and take appropriate action under s. 456.065.

Page 6 of 13

	39-00727A-20 20201764
175	involving a planned out-of-hospital birth.
176	(a) The panel shall be composed of one obstetrical medical
177	physician, one obstetrical osteopathic physician, one certified
178	nurse midwife, one paramedic, and one midwife, each of whom must
179	have experience in out-of-hospital births and be appointed by
180	the applicable board or council. The State Surgeon General or
181	his or her designee shall serve as the chair and a nonvoting
182	member of the panel. The panel shall meet quarterly and as often
183	as necessary to perform its duties under this subsection and may
184	conduct its meetings using any method of telecommunication.
185	Panel members shall serve without compensation but may receive
186	reimbursement for per diem and travel expenses as provided in s.
187	<u>112.061.</u>
188	(b) Based on its review of reported adverse incidents under
189	this subsection, the panel shall collaborate with experts in
190	data collection and public health to identify any patterns or
191	trends linking certain adverse incidents to any licensed health
192	care practitioner providing planned out-of-hospital births,
193	identify causes for such patterns or trends, and make
194	recommendations for changes to address causes for adverse
195	incidents identified in the panel's review.
196	(c) By July 1 of each year, the panel shall report its
197	collaborative findings and recommendations to the department,
198	the Board of Medicine, the Board of Osteopathic Medicine, the
199	Board of Nursing, and the Council of Licensed Midwifery.
200	(5)(a) Using data collected from adverse incident reports
201	submitted under this section, from certificates of live birth
202	and certificates of fetal death filed with its Office of Vital
203	Statistics, and from information submitted by licensed midwives

Page 7 of 13

	39-00727A-20 20201764
204	to the Council of Licensed Midwifery, the department or its
205	designee shall, at a minimum:
206	1. Analyze data relating to the frequency and nature of
207	adverse incidents in planned out-of-hospital births;
208	2. Identify the rate of adverse incidents by the type of
209	adverse incident and attending health care practitioners or
210	unlicensed individuals;
211	3. Identify any patterns or trends linking types of adverse
212	incidents to attending health care practitioners or unlicensed
213	individuals, and study causes for such patterns or trends;
214	4. Compare the findings to any comparable research and data
215	associated with out-of-hospital births available from other
216	states; and
217	5. Make recommendations for policy changes that may reduce
218	the rate of adverse incidents in planned out-of-hospital births
219	in this state.
220	(b) By July 1 of each year, the department shall submit a
221	report of its findings and any recommendations to the Governor,
222	the President of the Senate, and the Speaker of the House of
223	Representatives. The report shall also be published on the
224	department's website. All information in the report must be
225	deidentified.
226	<u>(6)</u> (4) The department shall adopt rules to implement this
227	section and shall develop a form to be used for the reporting of
228	adverse incidents.
229	Section 4. Section 456.0496, Florida Statutes, is created
230	to read:
231	456.0496 Out-of-hospital births; continuing education
232	requirements; responsibilities; violations and penalties;
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Page 8 of 13

1	39-00727A-20 20201764
233	grounds for discipline; enforcement
234	(1) CONTINUING EDUCATION REQUIREMENTS
235	(a) A licensed health care practitioner who provides out-
236	of-hospital births shall biennially satisfy the following
237	continuing education hours as a condition for renewal of his or
238	her license:
239	1. Three hours of instruction on the risk of complications
240	during pregnancy, labor, and delivery.
241	2. Four hours of instruction on ethics and collaborative
242	care, including informed consent, patient confidentiality,
243	patient relationships, transportation from a home or birth
244	center to a hospital, and malpractice and negligence.
245	(b) The department shall prescribe by rule continuing
246	education requirements as a condition for renewal of a license.
247	The criteria for continuing education programs must be approved
248	by the department. Any individual, institution, organization, or
249	agency that is approved by the department to provide continuing
250	education programs for the purpose of license renewal to a
251	licensed health care practitioner providing out-of-hospital
252	births must demonstrate that such programs comply with all of
253	the following requirements:
254	1. The programs have clinical relevance to practitioners
255	providing out-of-hospital birth.
256	2. The programs are at least 1 clock hour in duration.
257	3. The programs have an organized structure with objectives
258	and expected outcomes.
259	4. Each presenter, instructor, or facilitator of a program
260	is a recognized professional, such as a physician, nurse,
261	certified nurse midwife, psychologist, or licensed midwife.

Page 9 of 13

	39-00727A-20 20201764_
262	(2) RESPONSIBILITIES OF A HEALTH CARE PRACTITIONERA
263	licensed health care practitioner providing out-of-hospital
264	births shall do all of the following:
265	(a) Upon acceptance of a patient into care, advise the
266	patient of the clinical outcomes of births in low-risk patients
267	during an out-of-hospital birth and any increased risks
268	associated with an individual having a vaginal birth after
269	having a caesarean section, a breech birth, or a multiple
270	gestation pregnancy. The licensed health care practitioner
271	providing out-of-hospital births shall further advise, but may
272	not require, the patient to consult an obstetrician for more
273	information related to such clinical outcomes and increased
274	risks.
275	(b) Prepare a written plan of action with the family to
276	ensure continuity of medical care throughout labor and delivery
277	and to provide for immediate medical care if an emergency
278	arises. The family should have specific plans for medical care
279	throughout the prenatal, intrapartal, and postpartal periods.
280	(c) If a home birth is planned, instruct the patient and
281	family regarding the preparation of the home and ensure
282	availability of equipment and supplies needed for delivery and
283	infant care.
284	(d) Instruct the patient in personal hygiene and sanitary
285	measures as they relate to pregnancy and in nutrition as it
286	relates to prenatal care.
287	(e) Maintain equipment and supplies required for providing
288	care during the intrapartum and immediate postpartum periods in
289	an out-of-hospital setting.
290	(f) Upon initial contact with the patient during the
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Page 10 of 13

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291intrapartal period, measure and record the vital signs of the292mother and fetus to serve as a baseline during labor and293delivery.294(g) Transfer care of the patient to a hospital with295obstetrical services in accordance with the written emergency296plan if any of the following occurs or presents during labor or297delivery or immediately thereafter:2981. An unexpected nonvertex presentation of the fetus;2992. Indication that the mother's uterus has ruptured;3003. Evidence of severe and persistent fetal or maternal301distress;3024. Pregnancy-induced hypertension;3035. An umbilical cord prolapse;3046. Active infectious disease process; or3057. Any other severe emergent condition.306(3) INFORMED CONSENTThe department shall develop a307uniform patient informed consent form to be used by the licensed308health care practitioner providing out-of-hospital births to309inform the patient of the health care practitioner's310gualifications and the nature and risk of the procedures to be311petformed by the health care practitioner and to obtain the322patient's consent for the provision of out-of-hospital birth333services. The form must be signed by the patient and the health334care practitioner providing out-of-hospital births, and a copy335must be provided to the patient. The form shall include, at a336minimum, all of the follow		39-00727A-20 20201764
293delivery.294(g) Transfer care of the patient to a hospital with295obstetrical services in accordance with the written emergency296plan if any of the following occurs or presents during labor or297delivery or immediately thereafter:2981. An unexpected nonvertex presentation of the fetus;2992. Indication that the mother's uterus has ruptured;3003. Evidence of severe and persistent fetal or maternal301distress;3024. Pregnancy-induced hypertension;3035. An umbilical cord prolapse;3046. Active infectious disease process; or3057. Any other severe emergent condition.306(3) INFORMED CONSENTThe department shall develop a307uniform patient informed consent form to be used by the licensed308health care practitioner providing out-of-hospital births to319inform the patient of the health care practitioner's310gualifications and the nature and risk of the procedures to be311performed by the health care practitioner and to obtain the312patient's consent for the provision of out-of-hospital birth313services. The form must be signed by the patient and the health314care practitioner providing out-of-hospital births, and a copy315must be provided to the patient. The form shall include, at a316minimum, all of the following:317(a) A statement advising the patient of the clinical318outcomes of births in low-risk patients during an out-of- <td>291</td> <td>intrapartal period, measure and record the vital signs of the</td>	291	intrapartal period, measure and record the vital signs of the
294295296(g) Transfer care of the patient to a hospital with295obstetrical services in accordance with the written emergency296plan if any of the following occurs or presents during labor or297delivery or immediately thereafter:2981. An unexpected nonvertex presentation of the fetus;2992. Indication that the mother's uterus has ruptured;3003. Evidence of severe and persistent fetal or maternal301distress;3024. Pregnancy-induced hypertension;3035. An umbilical cord prolapse;3046. Active infectious disease process; or3057. Any other severe emergent condition.306(3) INFORMED CONSENTThe department shall develop a307uniform patient informed consent form to be used by the licensed308health care practitioner providing out-of-hospital births to309inform the patient of the health care practitioner's310gualifications and the nature and risk of the procedures to be311patient's consent for the provision of out-of-hospital birth312services. The form must be signed by the patient and the health313care practitioner providing out-of-hospital births, and a copy314(a) A statement advising the patient of the clinical315outcomes of births in low-risk patients during an out-of-	292	mother and fetus to serve as a baseline during labor and
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3057. Any other severe emergent condition.306(3) INFORMED CONSENTThe department shall develop a307uniform patient informed consent form to be used by the licensed308health care practitioner providing out-of-hospital births to309inform the patient of the health care practitioner's310qualifications and the nature and risk of the procedures to be311performed by the health care practitioner and to obtain the312patient's consent for the provision of out-of-hospital birth313services. The form must be signed by the patient and the health314care practitioner providing out-of-hospital births, and a copy315must be provided to the patient. The form shall include, at a316minimum, all of the following:317(a) A statement advising the patient of the clinical318outcomes of births in low-risk patients during an out-of-	303	5. An umbilical cord prolapse;
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307 uniform patient informed consent form to be used by the licensed 308 health care practitioner providing out-of-hospital births to 309 inform the patient of the health care practitioner's 310 qualifications and the nature and risk of the procedures to be 311 performed by the health care practitioner and to obtain the 312 patient's consent for the provision of out-of-hospital birth 313 services. The form must be signed by the patient and the health 314 care practitioner providing out-of-hospital births, and a copy 315 must be provided to the patient. The form shall include, at a 316 minimum, all of the following: 317 (a) A statement advising the patient of the clinical 318 outcomes of births in low-risk patients during an out-of-	305	7. Any other severe emergent condition.
308 health care practitioner providing out-of-hospital births to 309 inform the patient of the health care practitioner's 310 qualifications and the nature and risk of the procedures to be 311 performed by the health care practitioner and to obtain the 312 patient's consent for the provision of out-of-hospital birth 313 services. The form must be signed by the patient and the health 314 care practitioner providing out-of-hospital births, and a copy 315 must be provided to the patient. The form shall include, at a 316 minimum, all of the following: 317 (a) A statement advising the patient of the clinical 318 outcomes of births in low-risk patients during an out-of-	306	(3) INFORMED CONSENTThe department shall develop a
309 <u>inform the patient of the health care practitioner's</u> 310 <u>qualifications and the nature and risk of the procedures to be</u> 311 <u>performed by the health care practitioner and to obtain the</u> 312 <u>patient's consent for the provision of out-of-hospital birth</u> 313 <u>services. The form must be signed by the patient and the health</u> 314 <u>care practitioner providing out-of-hospital births, and a copy</u> 315 <u>must be provided to the patient. The form shall include, at a</u> 316 <u>minimum, all of the following:</u> 317 <u>(a) A statement advising the patient of the clinical</u> 318 <u>outcomes of births in low-risk patients during an out-of-</u>	307	uniform patient informed consent form to be used by the licensed
310 <u>qualifications and the nature and risk of the procedures to be</u> 311 <u>performed by the health care practitioner and to obtain the</u> 312 <u>patient's consent for the provision of out-of-hospital birth</u> 313 <u>services. The form must be signed by the patient and the health</u> 314 <u>care practitioner providing out-of-hospital births, and a copy</u> 315 <u>must be provided to the patient. The form shall include, at a</u> 316 <u>minimum, all of the following:</u> 317 <u>(a) A statement advising the patient of the clinical</u> 318 <u>outcomes of births in low-risk patients during an out-of-</u>	308	health care practitioner providing out-of-hospital births to
311 performed by the health care practitioner and to obtain the 312 patient's consent for the provision of out-of-hospital birth 313 services. The form must be signed by the patient and the health 314 care practitioner providing out-of-hospital births, and a copy 315 must be provided to the patient. The form shall include, at a 316 minimum, all of the following: 317 (a) A statement advising the patient of the clinical 318 outcomes of births in low-risk patients during an out-of-	309	inform the patient of the health care practitioner's
312 patient's consent for the provision of out-of-hospital birth 313 services. The form must be signed by the patient and the health 314 care practitioner providing out-of-hospital births, and a copy 315 must be provided to the patient. The form shall include, at a 316 minimum, all of the following: 317 (a) A statement advising the patient of the clinical 318 outcomes of births in low-risk patients during an out-of-	310	qualifications and the nature and risk of the procedures to be
313 <u>services. The form must be signed by the patient and the health</u> 314 <u>care practitioner providing out-of-hospital births, and a copy</u> 315 <u>must be provided to the patient. The form shall include, at a</u> 316 <u>minimum, all of the following:</u> 317 <u>(a) A statement advising the patient of the clinical</u> 318 <u>outcomes of births in low-risk patients during an out-of-</u>	311	performed by the health care practitioner and to obtain the
314 <u>care practitioner providing out-of-hospital births, and a copy</u> 315 <u>must be provided to the patient. The form shall include, at a</u> 316 <u>minimum, all of the following:</u> 317 <u>(a) A statement advising the patient of the clinical</u> 318 <u>outcomes of births in low-risk patients during an out-of-</u>	312	patient's consent for the provision of out-of-hospital birth
315 <u>must be provided to the patient. The form shall include, at a</u> 316 <u>minimum, all of the following:</u> 317 <u>(a) A statement advising the patient of the clinical</u> 318 <u>outcomes of births in low-risk patients during an out-of-</u>	313	services. The form must be signed by the patient and the health
316 <u>minimum, all of the following:</u> 317 <u>(a) A statement advising the patient of the clinical</u> 318 <u>outcomes of births in low-risk patients during an out-of-</u>	314	care practitioner providing out-of-hospital births, and a copy
317 (a) A statement advising the patient of the clinical 318 outcomes of births in low-risk patients during an out-of-	315	must be provided to the patient. The form shall include, at a
318 outcomes of births in low-risk patients during an out-of-	316	minimum, all of the following:
	317	(a) A statement advising the patient of the clinical
319 hospital birth and any increased risks associated with having a	318	outcomes of births in low-risk patients during an out-of-
	319	hospital birth and any increased risks associated with having a

Page 11 of 13

	39-00727A-20 20201764
320	vaginal birth after having a caesarean section, a breech birth,
321	or a multiple gestation pregnancy.
322	(b) A detailed statement explaining to the patient hospital
323	admitting privileges and the requirements to obtain and maintain
324	such privileges.
325	(c) Disclosure of each hospital and specific department, if
326	any, where the health care practitioner providing out-of-
327	hospital births has been granted admitting privileges, including
328	the scope and duration of the admitting privileges, the current
329	contact information for the specific hospital or department that
330	has granted the health care practitioner admitting privileges,
331	and a copy of documentation from the hospital or department
332	providing proof of such admitting privileges. A health care
333	practitioner providing out-of-hospital births who does not have
334	admitting privileges at any hospital must explicitly state that
335	fact on the form.
336	(4) VIOLATIONS AND PENALTIES
337	(a) A person who knowingly conceals or fraudulently
338	misrepresents information or a requirement relating to the
339	practice of out-of-hospital birth commits a felony of the third
340	degree, punishable as provided in s. 775.082, s. 775.083, or s.
341	775.084.
342	(b) The fraudulent misrepresentation of a requirement
343	relating to the practice of out-of-hospital birth is grounds for
344	denial of a license or disciplinary action, as specified in s.
345	456.072(2).
346	(5) GROUNDS FOR DISCIPLINE; PENALTIES; ENFORCEMENTIf the
347	ground for disciplinary action is a first-time violation of a
348	practice act for unprofessional conduct, as used in ss.
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Page 12 of 13

	39-00727A-20 20201764
349	464.018(1)(h), $467.203(1)(f)$, $468.365(1)(f)$, and $478.52(1)(f)$,
350	and no actual harm to the patient occurred, the board or
351	department, as applicable, shall issue a citation in accordance
352	with s. 456.077 and assess a penalty as determined by rule of
353	the board or department.
354	Section 5. This act shall take effect July 1, 2020.