## As Passed by the House

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Sub. S. B. No. 124

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## ABILL

ГО	amend sections 2317.54, 3702.30, 3702.31, 3727.09,	1
	3727.10, 4765.01, and 4765.50 and to enact sections	2
	3702.32, 3727.101, and 3727.102 of the Revised Code	3
	relative to sanctions for a health care facility's	4
	violations of licensing requirements and quality	į
	standards, injunctions to enjoin such violations,	6
	informed consent compliance requirements for	-
	ambulatory surgical facility physicians, expanded	8
	health care facility rule making authority of the	9
	Director of Health, and implementation of	10
	requirements applicable to trauma centers.	11

## BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 2317.54, 3702.30, 3702.31, 3727.09,	12
3727.10, 4765.01, and 4765.50 be amended and sections 3702.32,	13
3727.101, and 3727.102 of the Revised Code be enacted to read as	14
follows:	15

Sec. 2317.54. No hospital, home health agency, ambulatory surgical facility, or provider of a hospice care program shall be held liable for a physician's failure to obtain an informed consent from his the physician's patient prior to a surgical or medical procedure or course of procedures, unless the physician is an employee of the hospital, home health agency, ambulatory surgical facility or provider of a hospice care program.

Written consent to a surgical or medical procedure or course of procedures shall, to the extent that it fulfills all the requirements in divisions (A), (B), and (C) of this section, be presumed to be valid and effective, in the absence of proof by a preponderance of the evidence that the person who sought such consent was not acting in good faith, or that the execution of the consent was induced by fraudulent misrepresentation of material facts, or that the person executing the consent was not able to communicate effectively in spoken and written English or any other language in which the consent is written. Except as herein provided, no evidence shall be admissible to impeach, modify, or limit the authorization for performance of the procedure or procedures set forth in such written consent.

- (A) The consent sets forth in general terms the nature and purpose of the procedure or procedures, and what the procedures are expected to accomplish, together with the reasonably known risks, and, except in emergency situations, sets forth the names of the physicians who shall perform the intended surgical procedures.
- (B) The person making the consent acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.
  - (C) The consent is signed by the patient for whom the

procedure is to be performed, or, if the patient for any reason including, but not limited to, competence, infancy, or the fact that, at the latest time that the consent is needed, the patient is under the influence of alcohol, hallucinogens, or drugs, lacks legal capacity to consent, by a person who has legal authority to consent on behalf of such patient in such circumstances.

Any use of a consent form that fulfills the requirements stated in divisions (A), (B), and (C) of this section has no effect on the common law rights and liabilities, including the right of a physician to obtain the oral or implied consent of a patient to a medical procedure, that may exist as between

physicians and patients on July 28, 1975.

As used in this section the term "hospital" has the meaning set forth in division (D) of section 2305.11 of the Revised Code; "home health agency" has the meaning set forth in division (A) of former section 3701.88 of the Revised Code; "ambulatory surgical facility" has the meaning as in division (A) of section 3702.30 of the Revised Code; and "hospice care program" has the meaning set forth in division (A) of section 3712.01 of the Revised Code. The provisions of this division apply to hospitals, doctors of medicine, doctors of osteopathic medicine, and doctors of podiatric medicine.

## Sec. 3702.30. (A) As used in this section:

- (1) "Ambulatory surgical facility" means a facility, whether or not part of the same organization as a hospital, that is located in a building distinct from another in which inpatient care is provided, and to which any of the following apply:
- (a) Outpatient surgery is routinely performed in the facility\_ and the facility functions separately from a hospital's inpatient surgical service and from the offices of private physicians, podiatrists, and dentists+.

(b) Anesthesia is administered in the facility by an	78
anesthesiologist or certified registered nurse anesthetist, and	79
the facility functions separately from a hospital's inpatient	80
surgical service and from the offices of private physicians,	81
podiatrists, and dentists;	82

- (c) The facility applies to be certified by the United States health care financing administration as an ambulatory surgical center for purposes of reimbursement under Part B of the medicare program, Part B of Title XVIII of the "Social Security Act," 49 Stat. 620 (1935), 42 U.S.C.A. 301, as amended+.
- (d) The facility applies to be certified by a national accrediting body approved by the health care financing administration for purposes of deemed compliance with the conditions for participating in the medicare program as an ambulatory surgical center;
- (e) The facility bills or receives from any third-party payer, governmental health care program, or other person or government entity any ambulatory surgical facility fee that is billed or paid in addition to any fee for professional services+.
- (f) The facility is held out to any person or government 97 entity as an ambulatory surgical facility or similar facility by 98 means of signage, advertising, or other promotional efforts. 99

"Ambulatory surgical facility" does not include a hospital 100 emergency department.

- (2) "Ambulatory surgical facility fee" means a fee for certain overhead costs associated with providing surgical services in an outpatient setting. A fee is an ambulatory surgical facility fee only if it directly or indirectly pays for costs associated with any of the following:
- (a) Use of operating and recovery rooms, preparation areas, 107 and waiting rooms and lounges for patients and relatives; 108

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(b) Administrative functions, record keeping, housekeeping,	109
utilities, and rent;	110
(c) Services provided by nurses, orderlies, technical	111
personnel, and others involved in patient care related to	112
providing surgery.	113
"Ambulatory surgical facility fee" does not include any	114
additional payment in excess of a professional fee that is	115
provided to encourage physicians, podiatrists, and dentists to	116
perform certain surgical procedures in their office or their group	117
practice's office rather than a health care facility, if the	118
purpose of the additional fee is to compensate for additional cost	119
incurred in performing office-based surgery.	120
(3) "Governmental health care program" has the same meaning	121
as in section 4731.65 of the Revised Code.	122
(4) "Health care facility" means any of the following:	123
(a) An ambulatory surgical facility;	124
(b) A freestanding dialysis center;	125
(c) A freestanding inpatient rehabilitation facility;	126
(d) A freestanding birthing center;	127
(e) A freestanding radiation therapy center;	128
(f) A freestanding or mobile diagnostic imaging center.	129
(5) "Metropolitan statistical area" has the same meaning as	130
in section 3702.51 of the Revised Code.	131
(6) "Third-party payer" has the same meaning as in section	132
3901.38 of the Revised Code.	133
(B) By rule adopted in accordance with sections 3702.12 and	134
3702.13 of the Revised Code, the director of health shall	135
establish quality standards for health care facilities. The	136
standards may incorporate accreditation standards or other quality	137

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standards established by any entity recognized by the director.	139
The rules shall be adopted so as to cause the standards to take	140
effect on March 31, 1996.	110
(C) Every ambulatory surgical facility shall require that	141
each physician who practices at the facility comply with all	142
relevant provisions in the Revised Code that relate to the	143
obtaining of informed consent from a patient.	144
(D) The director shall issue a license to each health care	145
facility that makes application for a license and demonstrates to	146
the director that it meets the quality standards established $\underline{b}\underline{y}$	147
the rules adopted under division (B) of this section, except that	148
if a health care facility located in a metropolitan statistical	149
area applies for a license on or after March 31, 1996, and at the	150
time the license is to take effect the quality standards are not	151
yet in effect, the director shall issue the license without a	152
demonstration that the health care facility meets quality	153
standards and satisfies the informed consent compliance	154
requirements specified in division (C) of this section.	155
$\frac{(D)}{(E)(1)}$ No health care facility shall operate without a	156
license issued under this section.	157
(2) If the department of health finds that a physician who	158
practices at a health care facility is not complying with any	159
provision of the Revised Code related to the obtaining of informed	160
consent from a patient, the department shall report its finding to	161
the state medical board, the physician, and the health care	162
facility.	163
(3) This division does not create, and shall not be construed	164
as creating, a new cause of action or substantive legal right	165
against a health care facility and in favor of a patient who	166
allegedly sustains harm as a result of the failure of the	167
patient's physician to obtain informed consent from the patient	168

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prior to performing a procedure on or otherwise caring for the	169
patient in the health care facility.	170
$\frac{(E)}{(F)}$ The rules adopted under division (B) of this section	171
shall include provisions all of the following:	172
(1) Provisions governing application for, renewal,	173
suspension, and revocation of licenses a license under this	174
section;	175
(2) Provisions governing orders issued pursuant to section	176
3702.32 of the Revised Code for a health care facility to cease	177
its operations or to prohibit certain types of services provided	178
by a health care facility;	179
(3) Provisions governing the imposition under section 3702.32	180
of the Revised Code of civil penalties for violations of this	181
section or the rules adopted under this section, including a scale	182
for determining the amount of the penalties.	183
Sec. 3702.31. (A) The quality monitoring and inspection fund	184
is hereby created in the state treasury. The director of health	185
shall use the fund to administer and enforce this section and	186
sections 3702.11 to 3702.20 and, 3702.30, and 3702.32 of the	187
Revised Code and rules adopted pursuant to those sections. The	188
director shall deposit in the fund any moneys collected pursuant	189
to this section or section 3702.32 of the Revised Code. All	190
investment earnings of the fund shall be credited to the fund.	191
(B) The director of health shall adopt rules pursuant to	192
Chapter 119. of the Revised Code establishing fees for both of the	193
following:	194
(1) Initial and renewal license applications submitted under	195
section 3702.30 of the Revised Code. The fees established under	196
division (B)(1) of this section shall not exceed the actual and	197
necessary costs of performing the activities described in division	198

inspection.

The court shall grant an injunction upon a showing that the

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respondent named in the petition is providing the types of	260
services prohibited by the director's order.	261
(C) If, after making its reports as provided in division	262
(E)(2) of section 3702.30 of the Revised Code, the department of	263
health finds that a physician has continued to engage at the same	264
health care facility in a pattern of repeating the same violation	265
and that the health care facility has failed to take reasonable	266
steps to ensure that the physician does not continue the same	267
violation at the health care facility, the department may, after	268
providing the health care facility an opportunity for a hearing	269
pursuant to Chapter 119. of the Revised Code, impose a civil	270
penalty on the health care facility. The penalty shall be not less	271
than one thousand dollars and not more than fifty thousand	272
dollars.	273
(D) If the director of health determines that a health care	274
facility has violated any provision of section 3702.30 of the	275
Revised Code, other than a violation of division (E)(1) or (2) of	276
that section, any provision of Chapter 3701-83 of the	277
Administrative Code, or any other rule adopted by the director of	278
health under section 3702.30 of the Revised Code, the director may	279
do any or all of the following:	280
(1) Provide an opportunity for the health care facility to	281
correct the violation within a specified period of time;	282
(2) Revoke, suspend, or refuse to renew the health care	283
<pre>facility's license;</pre>	284
(3) Prior to or during the pendency of an administrative	285
hearing under Chapter 119. of the Revised Code, issue an order	286
that prohibits the health care facility from performing certain	287
types of services;	288
(4) Provide an opportunity for the health care facility to	289
correct the violation;	290

(5) Impose a civil penalty of not less than one thousand	291
dollars and not more than two hundred fifty thousand dollars upon	292
the health care facility for the violation;	293
(6) Impose an additional civil penalty of not less than five	294
hundred dollars and not more than ten thousand dollars for each	295
day that the health care facility fails to correct the violation.	296
(E) If a health care facility subject to an order issued	297
under division (C)(2) of this section continues to provide the	298
types of services prohibited by the order, the director of health	299
may file a petition in the court of common pleas of the county in	300
which the facility is located for an injunction enjoining the	301
facility from performing those types of services. The court shall	302
grant an injunction upon a showing that the respondent named in	303
the petition is providing the types of services prohibited by the	304
director's order.	305
(F) The director shall deposit all moneys collected as civil	306
penalties under this section into the quality monitoring and	307
inspection fund created under section 3702.31 of the Revised Code	308
for use in accordance with that section.	309
Sec. 3727.09. (A) As used in this section and section	310
sections 3727.10 and 3727.101 of the Revised Code:	311
(1) "Trauma," "trauma care," <del>and</del> "trauma center <u>,</u> " <u>"trauma</u>	312
<pre>patient," "pediatric," and "adult" have the same meanings as in</pre>	313
section 4765.01 of the Revised Code.	314
(2) "Stabilize" and "transfer" have the same meanings as in	315
section 1753.28 of the Revised Code.	316
(B) Not later than two years On and after the effective date	317
of this section November 3, 2002, each hospital in this state that	318
is not a trauma center shall adopt protocols for adult and	319

pediatric trauma care provided in or by that hospital; each

(c) Advance notification and appropriate medical consultation

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center;

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with the trauma center to which a trauma patient is being, or will	352
be, transferred;	353
(d) Procedures for selecting an appropriate method of	354
transportation and the hospital responsible for arranging or	355
providing the transportation;	356
(e) Confirmation of the ability of the persons and vehicle	357
that will transport a trauma patient to provide appropriate adult	358
or pediatric trauma care;	359
(f) Assured communication with, and appropriate medical	360
direction of, the persons transporting a trauma patient to a	361
trauma center;	362
(g) Identification and timely transfer of appropriate medical	363
records of the trauma patient being transferred;	364
(h) The hospital responsible for care of a patient in	365
transit;	366
(i) The responsibilities of the physician attending a patient	367
and, if different, the physician who authorizes a transfer of the	368
patient;	369
(j) Procedures for determining, in consultation with an	370
appropriate adult or pediatric trauma center and the persons who	371
will transport a trauma patient, when transportation of the	372
patient to a trauma center may be delayed for either of the	373
following reasons:	374
(i) Immediate transfer of the patient is unsafe due to	375
adverse weather or ground conditions.	376
(ii) No trauma center is able to provide appropriate adult or	377
pediatric trauma care to the patient without undue delay.	378
(4) Peer review and quality assurance procedures for adult	379
and pediatric trauma care provided in or by the hospital.	380

- (C)(1) Not later than two years On and after the effective 381

  date of this section November 3, 2002, each hospital shall enter 382

  into all of the following written agreements unless otherwise 383

  provided in division (C)(2) of this section: 384
- (a) An agreement with one or more adult trauma centers in 385 each level of categorization as a trauma center higher than the 386 hospital that governs the transfer of adult trauma patients from 387 the hospital to those trauma centers; 388
- (b) An agreement with one or more pediatric trauma centers in 389 each level of categorization as a trauma center higher than the 390 hospital that governs the transfer of pediatric trauma patients 391 from the hospital to those trauma centers. 392
- (2) A level I or level II adult trauma center is not required to enter into an adult trauma patient transfer agreement with another hospital. A level I or level II pediatric trauma center is not required to enter into a pediatric trauma patient transfer agreement with another hospital. A hospital is not required to enter into an adult trauma patient transfer agreement with a level III or level IV adult trauma center, or enter into a pediatric trauma patient transfer agreement with a level III or level IV pediatric trauma center, if no trauma center of that type is reasonably available to receive trauma patients transferred from the hospital.
- (3) A trauma patient transfer agreement entered into by a hospital under division (C)(1) of this section shall comply with applicable federal and state laws and contain provisions conforming to the requirements for trauma care protocols set forth in division (B) of this section.
- (D) A hospital shall make trauma care protocols it adopts 409 under division (B) of this section and trauma patient transfer 410 agreements it adopts under division (C) of this section available 411

Sec. 3727.101. (A) If a hospital is seeking initial	443
verification as an adult or pediatric trauma center, verification	444
at a different level, or reverification after having ceased to be	445
verified for one year or longer, the hospital shall submit an	446
application to the American college of surgeons for a consultation	447
visit. If a hospital is seeking reverification after having ceased	448
to be verified for less than one year, the hospital shall submit	449
an application for either a consultation visit or a reverification	450
visit, except when operating pursuant to division (C)(1)(b) of	451
this section.	452
The hospital shall undergo the visit and obtain a written	453
report of the results of the visit. If the report is not obtained	454
by the date that occurs one year after the application for the	455
visit is submitted, the hospital shall submit a new application.	456
(B) Not later than one year after obtaining a report under	457
division (A) of this section, a hospital may apply to the American	458
college of surgeons for verification or reverification as an adult	459
or pediatric trauma center if, based on the report, all of the	460
following occur:	461
(1) The hospital's chief medical officer and chief executive	462
officer certify in writing to the hospital's governing board that	463
the hospital is committed and able to provide adult or pediatric	464
trauma care consistent with the level of verification or	465
reverification being sought.	466
(2) The hospital's governing board adopts a resolution	467
stating that the hospital is committed and able to provide adult	468
or pediatric trauma care consistent with the level of verification	469
or reverification being sought.	470
(3) The hospital's governing board approves a written plan	471
and timetable for obtaining the level of verification or	472
reverification being sought, including provisions for correcting	473

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at the earliest practicable date any deficiencies identified in	474
the report obtained pursuant to division (A) of this section.	475
(C)(1) A hospital may operate as an adult or pediatric trauma	476
center under provisional status, as follows:	477
(a) On submission of an application under division (B) of	478
this section;	479
(b) Until it receives the final result of its reverification	480
if the application was submitted within one year before it ceased	481
to be verified.	482
(2) A hospital operating as an adult or pediatric trauma care	483
center under provisional status is subject to both of the	484
<pre>following:</pre>	485
(a) The hospital shall limit its provisional status	486
activities to those activities authorized by the level of	487
verification or reverification being sought.	488
(b) The hospital shall make a reasonable, good faith effort	489
to comply with all requirements established by the American	490
college of surgeons that must be met for the level of verification	491
or reverification being sought.	492
(D)(1) A hospital shall cease to operate as an adult or	493
pediatric trauma center under provisional status if any of the	494
following applies:	495
(a) The application for verification or reverification is	496
denied, suspended, terminated, or withdrawn.	497
(b) In the case of a hospital seeking initial verification,	498
verification at a different level, or reverification after having	499
ceased to be verified for one year or longer, the hospital has not	500
obtained verification or reverification by the date that occurs	501
eighteen months after commencing to operate under provisional	502
status.	503

(c) In the case of a hospital seeking reverification after	504
having ceased to be verified for less than one year, the hospital	505
has not obtained reverification by the date that occurs one year	506
after commencing to operate under provisional status.	507
(2) A hospital that ceases to operate as an adult or	508
pediatric trauma center under provisional status pursuant to	509
division (D)(1) of this section shall do all of the following:	510
(a) Except as otherwise provided by federal law, at the	511
earliest practicable date transfer to one or more appropriate	512
trauma centers all trauma patients in the hospital to whom the	513
hospital is not permitted to provide trauma care.	514
(b) Promptly comply with section 3727.10 of the Revised Code	515
according to its current status.	516
(c) Not later than one hundred eighty days after ceasing to	517
operate under provisional status, comply with section 3727.09 of	518
the Revised Code according to its current status.	519
(3) A hospital that ceases to operate as an adult or	520
pediatric trauma center under provisional status may not operate	521
as an adult or pediatric trauma center under provisional status	522
until two years have elapsed since it ceased to operate under that	523
status.	524
(E) With respect to the availability of documents and other	525
information prepared pursuant to this section, an adult or	526
pediatric trauma center operating under provisional status is	527
subject to both of the following:	528
(1) The trauma center shall make available for public	529
inspection during normal working hours a copy of the	530
certification, resolution, and application prepared pursuant to	531
division (B) of this section. On request, the trauma center shall	532
provide a copy of the documents. A reasonable fee may be charged	533
to cover the necessary expenses incurred in furnishing the copies,	534

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section 3727.101 of the Revised Code.

place of its provisional status.

status.

(D) The hospital changes the level of verification or

(E) The hospital ceases to operate under its provisional

(F) The hospital receives verification or reverification in

reverification it is seeking under its provisional status.

Sec. 4765.01. As used in this chapter:	595
(A) "First responder" means an individual who holds a	596
current, valid certificate issued under section 4765.30 of the	597
Revised Code to practice as a first responder.	598
(B) "Emergency medical technician-basic" or "EMT-basic" means	599
an individual who holds a current, valid certificate issued under	600
section 4765.30 of the Revised Code to practice as an emergency	601
medical technician-basic.	602
(C) "Emergency medical technician-intermediate" or "EMT-I"	603
means an individual who holds a current, valid certificate issued	604
under section 4765.30 of the Revised Code to practice as an	605
emergency medical technician-intermediate.	606
(D) "Emergency medical technician-paramedic" or "paramedic"	607
means an individual who holds a current, valid certificate issued	608
under section 4765.30 of the Revised Code to practice as an	609
emergency medical technician-paramedic.	610
(E) "Ambulance" means any motor vehicle that is used, or is	611
intended to be used, for the purpose of responding to emergency	612
medical situations, transporting emergency patients, and	613
administering emergency medical service to patients before,	614
during, or after transportation.	615
(F) "Cardiac monitoring" means a procedure used for the	616
purpose of observing and documenting the rate and rhythm of a	617
patient's heart by attaching electrical leads from an	618
electrocardiograph monitor to certain points on the patient's body	619
surface.	620
(G) "Emergency medical service" means any of the services	621
described in sections 4765.35, 4765.37, 4765.38, and 4765.39 of	622
the Revised Code that are performed by first responders, emergency	623
medical technicians-basic, emergency medical	624

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(D) A person who is performing the functions of a first responder, EMT-basic, EMT-I, or paramedic under the authority of the laws of a jurisdiction other than this state, who is employed by or serves as a volunteer with an emergency medical service organization based in that state, and provides emergency medical services to or transportation of a patient in this state is not in violation of division (A) of this section.

entity actually provides emergency medical services.

A person who is performing the functions of a first responder, EMT-basic, EMT-I, or paramedic under a reciprocal agreement authorized by section 4765.10 of the Revised Code is not in violation of division (A) of this section.

- (E) Beginning two years On and after the effective date of this amendment November 3, 2002, no physician shall purposefully do any of the following:
- (1) Admit an adult trauma patient to a hospital that is not 736 an adult trauma center for the purpose of providing adult trauma 737 care; 738
- (2) Admit a pediatric trauma patient to a hospital that is
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  not a pediatric trauma center for the purpose of providing
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  pediatric trauma care;
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(3) Fail to transfer an adult or pediatric trauma patient to	742
an adult or pediatric trauma center in accordance with applicable	743
federal law, state law, and adult or pediatric trauma protocols	744
and patient transfer agreements adopted under section 3727.09 of	745
the Revised Code.	746
Section 2. That existing sections 2317.54, 3702.30, 3702.31,	747
3727.09, 3727.10, 4765.01, and 4765.50 of the Revised Code are	748
hereby repealed.	749
Section 3. Sections 3727.101 and 3727.102 of the Revised	750
Code, as enacted by this act, shall take effect on November 3,	751
2002, or the earliest time permitted by law, whichever is later.	752