S T A T E O F N E W Y O R K

4716

2015-2016 Regular Sessions

I N S E N A T E

April 10, 2015

Introduced by Sen. HANNON -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to enacting the "right to try act"

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. The public health law is amended by adding a new article 40-A to read as follows:

ARTICLE 40-A

ACCESS TO TREATMENTS FOR TERMINALLY ILL PATIENTS

SECTION 4050. SHORT TITLE.
4051. LEGISLATIVE INTENT.
4052. DEFINITIONS.
4053. AVAILABILITY OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS AND DEVICES.
4054. ACTION AGAINST HEALTH CARE PROVIDER.
4055. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS AND DEVICES.
4056. NO CAUSE OF ACTION CREATED.

S 4050. SHORT TITLE. THIS ARTICLE SHALL BE KNOWN AND MAY BE CITED AS THE "RIGHT TO TRY ACT".

S 4051. LEGISLATIVE INTENT. IT IS THE INTENT OF THE LEGISLATURE TO ALLOW FOR TERMINALLY ILL PATIENTS TO USE POTENTIALLY LIFE-SAVING INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS AND DEVICES.

S 4052. DEFINITIONS. AS USED IN THIS ARTICLE, THE FOLLOWING WORDS AND PHRASES SHALL HAVE THE FOLLOWING MEANINGS:

1. (A) "ELIGIBLE PATIENT" MEANS A PERSON WHO HAS:

(I) A TERMINAL ILLNESS, ATTESTED TO BY THE PATIENT'S TREATING PHYSICIAN;

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

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(II) CONSIDERED ALL OTHER TREATMENT OPTIONS CURRENTLY APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

(III) BEEN UNABLE TO PARTICIPATE IN A CLINICAL TRIAL FOR THE TERMINAL ILLNESS WITHIN ONE HUNDRED MILES OF THE PATIENT'S HOME ADDRESS FOR THE TERMINAL ILLNESS, OR NOT BEEN ACCEPTED TO THE CLINICAL TRIAL WITHIN ONE WEEK OF COMPLETION OF THE CLINICAL TRIAL APPLICATION PROCESS;

(IV) RECEIVED A RECOMMENDATION FROM HIS OR HER PHYSICIAN FOR AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE;

(V) GIVEN WRITTEN, INFORMED CONSENT FOR THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE OR, IF THE PATIENT IS A MINOR OR LACKS THE MENTAL CAPACITY TO PROVIDE INFORMED CONSENT, A PARENT OR LEGAL GUARDIAN HAS GIVEN WRITTEN, INFORMED CONSENT ON THE PATIENT'S BEHALF; AND

(VI) DOCUMENTATION FROM HIS OR HER PHYSICIAN THAT HE OR SHE MEETS THE REQUIREMENTS OF THIS PARAGRAPH.

(B) "ELIGIBLE PATIENT" SHALL NOT INCLUDE A PERSON BEING TREATED AS AN INPATIENT IN A HOSPITAL OPERATED PURSUANT TO ARTICLE TWENTY-EIGHT OF THIS CHAPTER.

2. "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE" MEANS A DRUG, BIOLOGICAL PRODUCT OR DEVICE THAT HAS SUCCESSFULLY COMPLETED PHASE ONE OF A CLINICAL TRIAL BUT HAS NOT YET BEEN APPROVED FOR GENERAL USE BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND REMAINS UNDER INVESTIGATION IN A UNITED STATES FOOD AND DRUG ADMINISTRATION-APPROVED CLINICAL TRIAL.

3. "TERMINAL ILLNESS" MEANS A CONDITION, ILLNESS OR INJURY FROM WHICH THERE IS NO RECOVERY AND WHICH REASONABLY CAN BE EXPECTED TO CAUSE DEATH WITHIN ONE YEAR.

4. "WRITTEN, INFORMED CONSENT" MEANS A WRITTEN DOCUMENT SIGNED BY THE PATIENT, AND ATTESTED TO BY THE PATIENT'S PHYSICIAN AND A WITNESS THAT, AT A MINIMUM:

(A) EXPLAINS THE CURRENTLY APPROVED PRODUCTS AND TREATMENTS FOR THE DISEASE OR CONDITION FROM WHICH THE PATIENT SUFFERS;

(B) ATTESTS TO THE FACT THAT THE PATIENT CONCURS WITH HIS OR HER PHYSICIAN IN BELIEVING THAT ALL CURRENTLY APPROVED AND CONVENTIONALLY RECOGNIZED TREATMENTS ARE UNLIKELY TO PROLONG THE PATIENT'S LIFE;

(C) CLEARLY IDENTIFIES THE SPECIFIC PROPOSED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE THAT THE PATIENT IS SEEKING TO USE;

(D) DESCRIBES THE POTENTIALLY BEST AND WORST OUTCOMES OF USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE WITH A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME, INCLUDING THE POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT OR WORSE SYMPTOMS MIGHT RESULT, AND THAT DEATH COULD BE HASTENED BY THE PROPOSED TREATMENT, BASED ON THE PHYSICIAN'S KNOWLEDGE OF THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE PATIENT'S CONDITION;

(E) MAKES CLEAR THAT THE PATIENT'S HEALTH INSURER AND PROVIDER ARE NOT OBLIGATED TO PAY FOR ANY CARE OR TREATMENTS CONSEQUENT TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE;

(F) MAKES CLEAR THAT THE PATIENT'S ELIGIBILITY FOR HOSPICE CARE MAY BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT AND CARE MAY BE REINSTATED IF THE CURATIVE TREATMENT ENDS AND THE PATIENT MEETS HOSPICE ELIGIBILITY REQUIREMENTS;

(G) MAKES CLEAR THAT IN-HOME HEALTH CARE MAY BE DENIED IF TREATMENT BEGINS; AND

(H) STATES THAT THE PATIENT UNDERSTANDS THAT HE OR SHE IS LIABLE FOR ALL EXPENSES CONSEQUENT TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE, AND THAT THIS LIABILITY EXTENDS TO THE PATIENT'S

ESTATE, UNLESS A CONTRACT BETWEEN THE PATIENT AND THE MANUFACTURER OF THE DRUG, BIOLOGICAL PRODUCT OR DEVICE STATES OTHERWISE.

S 4053. AVAILABILITY OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS AND DEVICES. 1. A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE MAY MAKE AVAILABLE THE MANUFACTURER'S INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE TO ELIGIBLE PATIENTS PURSUANT TO THIS ARTICLE. THIS ARTICLE SHALL NOT BE DEEMED TO REQUIRE THAT A MANUFACTURER MAKE AVAILABLE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE TO AN ELIGIBLE PATIENT.

2. A MANUFACTURER MAY:

(A) PROVIDE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT RECEIVING COMPENSATION; OR

(B) REQUIRE AN ELIGIBLE PATIENT TO PAY THE COSTS OF OR THE COSTS ASSOCIATED WITH THE MANUFACTURE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

3. (A) NOTHING IN THIS ARTICLE SHALL BE DEEMED TO EXPAND THE COVERAGE PROVIDED IN ARTICLE FORTY-FOUR OF THIS CHAPTER, ARTICLES THIRTY-TWO AND FORTY-THREE OF THE INSURANCE LAW, AND TITLE ELEVEN OF ARTICLE FIVE OF THE SOCIAL SERVICES LAW.

(B) A HEALTH INSURANCE CARRIER MAY, BUT IS NOT REQUIRED TO, PROVIDE COVERAGE FOR THE COST OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

(C) AN INSURER MAY DENY COVERAGE TO AN ELIGIBLE PATIENT FROM THE TIME THE ELIGIBLE PATIENT BEGINS USE OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE THROUGH A PERIOD NOT TO EXCEED SIX MONTHS FROM THE TIME THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE IS NO LONGER USED BY THE ELIGIBLE PATIENT; EXCEPT THAT COVERAGE SHALL NOT BE DENIED FOR A PREEXISTING CONDITION AND FOR COVERAGE FOR BENEFITS WHICH COMMENCED PRIOR TO THE TIME THE ELIGIBLE PATIENT BEGINS USE OF SUCH DRUG, BIOLOGICAL PRODUCT OR DEVICE.

4. IF AN ELIGIBLE PATIENT DIES WHILE BEING TREATED BY AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE, THE PATIENT'S HEIRS SHALL NOT BE LIABLE FOR ANY OUTSTANDING DEBT RELATED TO THE TREATMENT OR LACK OF INSURANCE DUE TO THE TREATMENT.

S 4054. ACTION AGAINST HEALTH CARE PROVIDER. NOTWITHSTANDING ANY PROVISION OF LAW TO THE CONTRARY, NEITHER THE EDUCATION DEPARTMENT NOR THE STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT SHALL REVOKE, FAIL TO RENEW, SUSPEND OR TAKE ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE, BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE, SO LONG AS THE RECOMMENDATIONS ARE CONSISTENT WITH MEDICAL STANDARDS OF CARE. ACTING AGAINST A HEALTH CARE PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATION THAT A PATIENT HAVE ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE IS PROHIBITED.

S 4055. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS AND DEVICES. AN OFFICIAL, EMPLOYEE OR AGENT OF THIS STATE SHALL NOT BLOCK OR ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE. COUNSELING, ADVICE OR A RECOMMENDATION CONSISTENT WITH MEDICAL STANDARDS OF CARE FROM A LICENSED HEALTH CARE PROVIDER IS NOT A VIOLATION OF THIS SECTION.

S 4056. NO CAUSE OF ACTION CREATED. THIS ARTICLE SHALL NOT BE DEEMED TO CREATE A PRIVATE CAUSE OF ACTION AGAINST A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE OR AGAINST ANY OTHER PERSON OR ENTITY INVOLVED IN THE CARE OF AN ELIGIBLE PATIENT USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE, FOR ANY HARM DONE TO

THE ELIGIBLE PATIENT RESULTING FROM THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE SO LONG AS THE MANUFACTURER OR OTHER PERSON OR ENTITY IS COMPLYING IN GOOD FAITH WITH THE TERMS OF THIS ARTICLE; UNLESS THERE WAS A FAILURE TO EXERCISE REASONABLE CARE.

S 2. This act shall take effect immediately.