HB 3799 STAFF MEASURE SUMMARY

House Committee On Behavioral Health and Health Care

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Meeting Dates: 3/27, 4/3

WHAT THE MEASURE DOES:

The measure establishes a process by which a health care practitioner may offer to treat a patient who has a terminal disease or severe chronic disease with an investigational product not approved by the United States Food and Drug Administration (FDA).

Detailed Summary:

- Defines "attending physician," "capable," "consulting physician," "health care practitioner," "investigational product," "qualified," "severe chronic disease," and "terminal disease."
- **Patient Referrals** (Section 2)
  - Permits attending physician to refer a qualified patient to health care practitioner for treatment of terminal or severe chronic disease with a product not approved by the FDA if the treatment is only related to the terminal or severe chronic disease and the attending physician believes the patient is acting voluntarily.
  - Requires attending physician to provide specified information to patient prior to referral, including the patient's disease status, the physician's prognosis, the investigational nature of the drug and its possible ineffectiveness, potential risks, potential insurance coverage and patient costs, possible alternative treatments, and required liability waiver.
- **Investigational Treatment** (Section 3)
  - Permits health care practitioner to treat a qualified patient with a terminal or severe chronic disease with an investigational product not approved by the FDA if practitioner is acting within scope, patient is not compensated, a consulting physician confirms diagnosis and prognosis, the practitioner believes the patient is acting voluntarily, and the treatment is provided for no more than the cost of manufacturing and administrating the treatment.
  - Requires health care practitioner to not patient's insurer if patient accepts investigational treatment has health insurance.
- Requires patient to prove Oregon residency; specifies evidence that may be used to establish proof of residency.
- Requires attending physician and health care practitioner to refer patient to counseling if physician believes patient is suffering from a psychiatric or psychological disorder or depression causing impaired judgment. Prohibits treatment via investigational product until counselor decides patient's judgement is not impaired.
- **Attestation Form** (Sections 5 and 6)
  - Requires patient electing to receive investigational treatment to sign and date form attesting to the election in the presence of two witnesses. Specifies that form must include attending physician's diagnosis and prognosis, a statement regarding the product's lack of FDA approval, a description of risks associated with the treatment, a waiver of liability, a provision authorizing use of information regarding treatment, and a statement signed by witnesses attesting that patient is capable and acting voluntarily.
  - Specifies that one witness must not be a relative of the patient, an individual who would be entitled to a portion of the patient's estate, or an owner, operator, or employee of a facility where the patient receives services. Specifies that neither witness may be the patient's attending physician.
  - Requires waiver of liability to be written in plain and simple language and specifies required elements.

- Exempts health care practitioners, organizations and associations, and manufacturers and distributers involved in the administration of an investigational treatment from civil and criminal liability. Specifies that liability exemption does not apply to acts or omissions that constitute gross negligence.
- Prohibits licensing boards, health care facilities, and professional organizations or associations from subjecting health care practitioner to discipline for participating in investigational treatment.
- Permits facilities and practitioners to prohibit administration of investigational treatment on premises owned or controlled by facility or practitioner. Permits licensing boards, health care facilities, and professional organizations or associations to impose discipline for violation of prohibition. Permits facility or practitioner to terminate lease or contract as penalty for violation.
- Specifies that insurer is not required to reimburse costs associated with undergoing investigational treatment or any adverse effect of undergoing treatment.
- Requires attending physician, health care practitioner who administers treatment, and consulting physician to file record with the Oregon Health Authority (OHA). Specifies that record must include documentation of any adverse effects, positive outcomes, costs, and patient demographics. Requires OHA to adopt rules to facilitate collection of information. Specifies that information collected by OHA is not a public record.
- Requires OHA to annually review a sample of records, make available to public an annual statistical report, and to report annually to the Legislative Assembly by February 1.

Fiscal impact: (info)
Revenue impact: (info)

ISSUES DISCUSSED:

EFFECT OF AMENDMENT:

No amendment.

BACKGROUND:

The United States Food and Drug Administration (FDA) has established an expanded access pathway for patients with serious or life-threating diseases to try investigational medical products outside of a clinical trial. Also known as "compassionate use," the expanded access pathway offers a treatment option for patients who have no comparable therapy to treat the disease.

House Bill 3799 establishes a process by which a health care practitioner may offer to treat a patient who has a terminal disease or severe chronic disease with an investigational product not approved by the United States Food and Drug Administration (FDA).