§ 263–1. Education on biological products

(a) Internet website

(1) In general

The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

(2) Content

Educational materials provided under paragraph (1) may include—

(A) explanations of key statutory and regulatory terms, including ''biosimilar'' and ''interchangeable'', and clarification regarding the use of interchangeable biosimilar biological products;

(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 262(k) of this title and reference products (as defined in section 262(i) of this title), including the standards for review and licensing of each such type of biological product.

(3) Format

The educational materials provided under paragraph (1) may be—

(A) in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

(4) Other information

In addition to the information described in paragraph (2), the Secretary shall continue to publish—

(A) the action package of each biological product licensed under subsection (a) or (k) of section 262 of this title; or

(B) the summary review of each biological product licensed under subsection (a) or (k) of section 262 of this title.

(5) Confidential and trade secret information

This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

(b) Continuing education

The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

(July 1, 1944, ch. 373, title III, § 352A, as added Pub. L. 117–8, § 2, Apr. 23, 2021, 135 Stat. 254.)

SUBPART 2—CLINICAL LABORATORIES

§ 263a. Certification of laboratories

(a) "Laboratory" or "clinical laboratory" defined

As used in this section, the term ''laboratory'' or ''clinical laboratory'' means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(b) Certificate requirement

No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d).

(2) Term

A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

(d) Requirements for certificates

(1) In general

A laboratory may be issued a certificate or have its certificate renewed if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the accreditation body which accredited the laboratory submits), an application—

(i) in such form and manner as the Secretary shall prescribe,

(ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

(I) the number and types of laboratory examinations and other procedures performed,

(II) the methodologies for laboratory examinations and other procedures employed, and