MEMORANDUM

To: School Superintendents, Principals and School Nurses

From: Cathy Danyluk, Director of Student Services

Date: April 27, 2018

Re: Senate Enrolled Act 52 – Low THC Hemp Extract (IC 24-4-21)

Background:

The Indiana General Assembly recently passed legislation, effective July 1, 2018, that establishes testing, packaging, and labeling requirements for distribution and retail sale of low THC hemp extract. The law defines "low THC hemp extract" as a product: (1) derived from Cannabis sativa L. that meets the definition of industrial hemp; (2) that contains not more than 0.3% delta-9-THC (including precursors); and (3) that contains no other controlled substances. This bill has implications for schools as some parents are asking school nurses to administer low THC hemp extract (CBD oil) to students during the school day.

Guidance:

It is recommended that schools have a school medication policy that addresses the topic of low THC hemp extract, including CBD oil, and includes the items listed below. Before a school administers a low THC hemp extract substance, at a minimum, all of the following criteria should be met:

- Parent has provided the school with written permission to administer this product to his/her child and has verified that the product was acquired from a retailer that meets the requirements listed in SEA 52;
- Product has come in original packaging and is unopened;
- Student’s health care provider has provided the school with a prescription to administer the substance which includes the dose, route and time of administration; and
- Product has been approved by: (1) the federal Food and Drug Administration or the federal Drug Enforcement Agency as a prescription or over the counter drug; or (2) meets the packaging requirements of SEA 52.
SEA 52 states that low THC hemp extract must be distributed in packaging that contains the following information:

1) A scannable bar code or QR code linked to a document that contains information with respect to the manufacture of the low THC hemp extract, including the:
   - (A) batch identification number;
   - (B) product name;
   - (C) batch date;
   - (D) expiration date, which must be not more than two (2) years from the date of manufacture;
   - (E) batch size;
   - (F) total quantity produced;
   - (G) ingredients used, including the:
     - (i) ingredient name;
     - (ii) name of the company that manufactured the ingredient;
     - (iii) company or product identification number or code, if applicable; and
     - (iv) ingredient lot number; and
   - (H) download link for a certificate of analysis for the low THC hemp extract.

2) The batch number.
3) The Internet address of a web site to obtain batch information.
4) The expiration date.
5) The number of milligrams of low THC hemp extract.
6) The manufacturer.
7) The fact that the product contains not more than three-tenths percent (0.3%) total delta-9-tetrahydrocannabinol (THC), including precursors, by weight.

Definitions:

- "Certificate of analysis" means a certificate from an independent testing laboratory describing the results of the laboratory's testing of a sample.

- "Independent testing laboratory" means a laboratory:
  (A) with respect to which no person having a direct or indirect interest in the laboratory also has a direct or indirect interest in a facility that:
    - (i) processes, distributes, or sells low THC hemp extract, or a substantially similar substance in another jurisdiction;
    - (ii) cultivates, processes, distributes, dispenses, or sells marijuana; or
    - (iii) cultivates, processes, or distributes industrial hemp; and
  (B) that is accredited as a testing laboratory to International Organization for Standardization (ISO) 17025 by a third party accrediting body such as the American Association for Laboratory Accreditation (A2LA) or Assured Calibration and Laboratory Accreditation Select Services (ACCLASS).
If you have any questions, please contact Jolene Bracale at (317) 232-0541 or jbracale@doe.in.gov.