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January 17, 2025

South Dakota State Legislature
House Committee on Health and Human Services
500 East Capitol Avenue
Pierre, SD 57501

Dear Members of the House Committee on Health and Human Services,

On behalf of the Alliance for Pharmacy Compounding, I am writing to express our support for **HB 1016**, particularly **Section 45**, which addresses the repeal of **36-11A-4.2**.

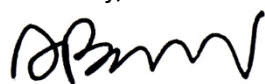
Section 45 eliminates the requirement that an outsourcing facility engaged in compounding non-patient-specific sterile and non-sterile drugs must be registered and inspected by the FDA before obtaining licensure from the South Dakota Board of Pharmacy.

This change is critical because the FDA registration and inspection process often takes several years to complete. During this time, patient access to compounded medications produced by outsourcing facilities is significantly delayed. By enabling outsourcing facilities to be licensed in South Dakota prior to FDA registration and inspection, HB 1016 ensures that patients in the state can more efficiently access the essential medications they need.

For these reasons, APC strongly supports the repeal of 36-11A-4.2 as proposed in Section 45 of HB 1016.

Thank you for the opportunity to provide these comments. If you have any questions, please feel free to contact me directly at scott@a4pc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott Brunner", is written over a horizontal line.

Scott Brunner, CAE
Chief Executive Officer

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 500 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.