



Colorado Department
of Public Health
and Environment

Information Sharing Issues: FDA and Colorado example

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Sunshine Laws



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- ▶ Regulations requiring openness in government
- ▶ Make meetings, records, votes, deliberations, investigations and other official actions available to public
- ▶ Specifics are often state-dependent

Colorado Open Records Act (CORA)



- ▶ Requires that most public records be available to the public.
- ▶ Unless specifically outlined in Colorado statute, all documents are open to the public and can be requested at any time
- ▶ Special exceptions:
 - Individually identified health information not subject to CORA
 - “Draft” documents or unfinished investigations are not released

CORA and sharing with FDA

- ▶ Potential conflicts, particularly if something is no longer considered “draft”
- ▶ Tension for FDA commissioned individuals – subject to both federal and state requirements
- ▶ May cause barriers to information sharing

Issues noted at state level

- ▶ Strict restrictions on information sharing can lead to timeliness issues
- ▶ Commercially confidential information – state staff sometimes unclear on what this means
- ▶ FDA Commissioned personnel
 - Limited in ability to share information
 - May affect ability to respond to health and safety issues
- ▶ Duplication of efforts can occur due to information sharing difficulties (i.e. repeat inspections, lab testing, etc)