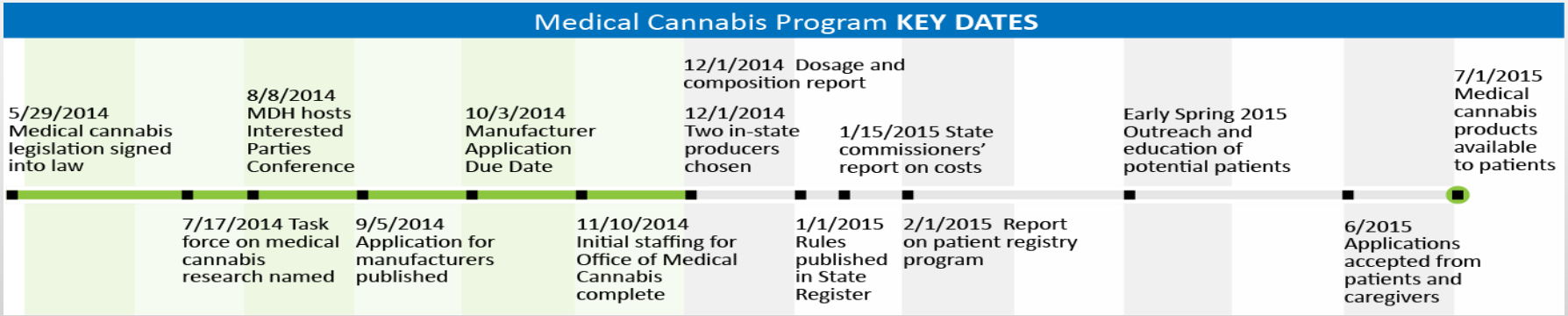
OMC UPDATE REPORT

Michelle Larson, Director
Darin Teske, Policy Analyst
Dr. Tom Arneson, Research Manager
Manny Munson-Regala, Asst. Commissioner

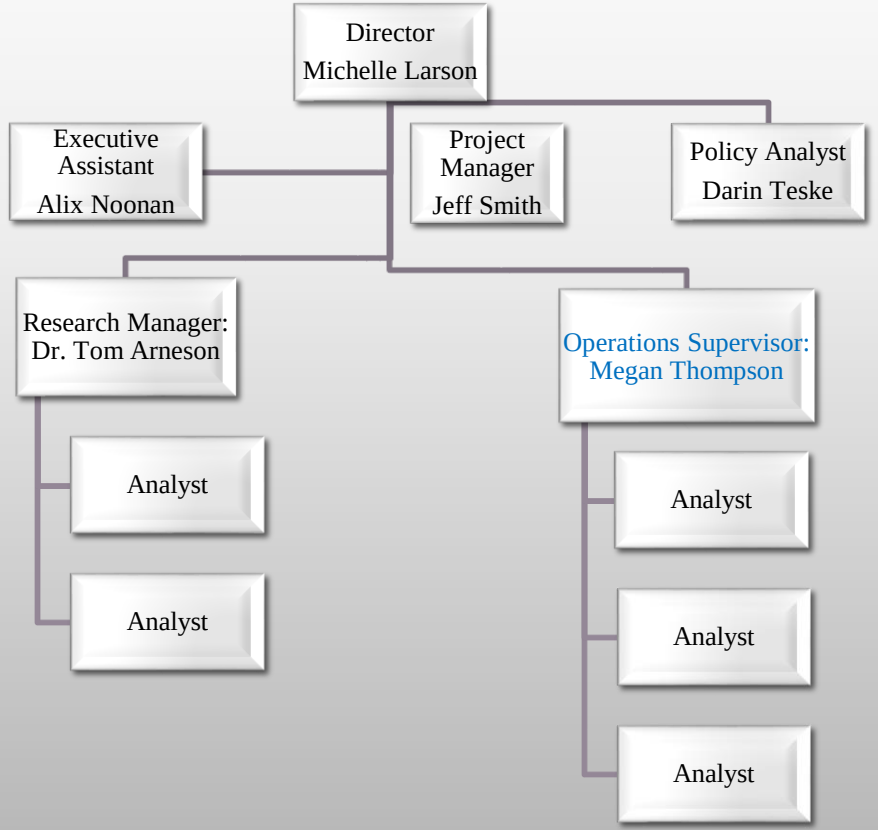
Agenda

- Implementation Overview- Michelle Larson
- Rulemaking- Darin Teske
- Dosages and Compositions Report- Dr. Tom Arneson
- Manufacturer Selection- Manny Munson-Regala

Overall Timeline



Hiring


Director
Michelle Larson
Executive Assistant
Alix Noonan
Project Manager
Jeff Smith
Policy Analyst
Darin Teske
Research Manager:
Dr. Tom Arneson
Operations Supervisor:
Megan Thompson
Analyst
Analyst
Analyst
Analyst
Analyst

IT and Business Development

- Continued work on IT solutions
  - Patient, Caregiver & Health Care Provider registration
  - Manufacturer patient verification and transactional data
  - Patient data to support research
- Business workflows also being finalized
- Patient Registration Goal Start Date: June 1, 2015
- Finalizing business requirements and workflow in next 2 weeks to be completed by 12/15
- On schedule

Other Work

- Potential Patient Survey
  - Get sense of likely patient demand
  - May impact location of distribution sites
  - Spring
- Outreach and Education
- Inspection Schedule
- Research Discussion with Manufacturers

Rulemaking- Expedited Rules

- Expedited Manufacturer Rules
  - At Office of Administrative Hearings for legal review.
    - Next steps: adopt or correct legal deficiencies.
- Expedited Patient-Health Care Practitioner Rules
  - Will be published in state register on December 15, beginning 30-day public comment period.
  - Next steps: after comment period, MDH revises and sends to OAH for legal review

Rulemaking- Formal Rulemaking

- Formal Rulemaking Process
  - Flesh out topics covered by expedited rules
  - May also include new topics
  - Informed by rulemaking advisory group
    - Solicitation/recruitment soon
    - Work targeted to begin late January 2015
    - Public input will be planned

Dosages and Compositions Report – Purpose:

Describe dosages and drug composition of cannabis agents used in human studies of Minnesota's qualifying medical conditions to inform creation of cannabis products and choice of dosages

Dosages and Compositions Report - Focus:

- Peer-reviewed scientific journals
- Human clinical trials and prospective observational studies
- Extracted or refined cannabis products or synthetic THC

Dosages and Compositions Report – Process:

- PubMed searches
- Access articles (MDH library)
- Read and create a summary
- Identify more studies in references
- Iterative – until leads exhausted

Dosages and Compositions Report – The Report

- 48 studies
- Summaries arranged by medical condition
- Overview of articles at top of each condition section
- Mention of trials in progress

Dosages and Compositions Report – The Summaries:

- Study design
- Number of patients
- Agent tested
- Starting dose and titration schedule
- Achieved dose
- Effectiveness measures
- Side Effects

Dosages and Compositions Report – Future:

- Update periodically (at least annually – probably more like every 4-6 months)

Path to becoming a Registered Manufacturer

All Applications

Letter of Intent?

Application Complete?

Criteria Pass/Fail?

Application Fee?

Complete Applications

Application Scoring

Semi-finalists

Site Visits

Finalists

Manufacturers

Minnesota Medical Solutions

- Dr. Kyle Kingsley CEO and Dr. Jon Thompson, Scientific Director
- Otsego, MN
  - Moorhead
  - Minneapolis
  - Rochester
  - Maple Grove

Leafline Labs LLC

- Peter Bachman, President with co-founders Dr. Gary Starr and Dr. Andy Bachman
  - Cottage Grove, MN
    - Eagan
    - Hibbing
    - St. Cloud
    - St. Paul

For more Information

- General Information: http://www.health.state.mn.us/topics/cannabis/index.html
- Rulemaking: http://www.health.state.mn.us/topics/cannabis/rulemaking/index.html
- Composition and Dosages Report: http://www.health.state.mn.us/topics/cannabis/practioner/dosage.pdf
- Manufacturer selection: http://www.health.state.mn.us/topics/cannabis/manufacture/index.html

Questions?