1. Statement of the need for the proposed major regulation.

The proposed major regulation is needed to implement the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), which requires the Department of Public Health (Department), in conjunction with the Bureau of Cannabis Control and the Department of Food and Agriculture, to license and regulate cannabis manufacturers in the commercial cannabis market. This proposed regulation will implement the Department's responsibilities related to licensing cannabis manufacturers, establishing manufacturing standards for cannabis products, and creating requirements for cannabis product packages and labels.

2. The categories of individuals and business enterprises who will be impacted by the proposed major regulation and the amount of the economic impact on each such category.

Current manufacturers of cannabis products and potential future manufacturers will face increased industry costs due to the proposed Department regulations of $138 million annually or 17.7 percent of manufacturer sales to cannabis retail dispensaries on an ongoing basis. Consumers will benefit because there will be a noticeable fall in the risk premium after manufactured cannabis is regulated. The risk premium is the additional amount that must be paid to compensate individuals for working in an industry that faces risk of law enforcement action. The decrease in the risk premium will increase supply, offset regulatory costs, and keep prices for manufactured cannabis from rising with regulations.

3. Description of all costs and all benefits due to the proposed regulatory change (calculated on an annual basis from estimated date of filing with the Secretary of State through 12 months after the estimated date the proposed major regulation will be fully implemented as estimated by the agency).

The regulatory costs to manufacturers include: labeling, testing, packaging, background checks, license fees, seller's fees, bonding, local permitting, facility compliance and video surveillance, closed-loop production systems, standard operating procedures, general licensing requirements such as serving size limits, inventory control and security. In the first year of implementation the estimated costs total $195 million. In the second year and ongoing, the expected annual industry costs are $138 million in inflation adjusted terms. Proposed regulations improve health benefits by putting in place packaging and labeling requirements, facility compliance requirements, and adulterated cannabis product restrictions. Overall, the result should be a safer product that minimizes any food-borne illnesses. Additionally, proposed regulations will establish safety standards for manufacturers conducting extraction through closed-loop extraction systems. Economic modeling indicates that the impact of CDPH regulations (and the accompanying statewide benefits) will increase retail sales $217 million annually ongoing (with a total lifetime statewide benefit of $7.2 billion).

4. Description of the 12-month period in which the agency estimates the economic impact of the proposed major regulation will exceed $50 million.

The Standardized Regulatory Impact Assessment (SRIA) initially conducted to analyze the economic impacts of proposed medicinal market-only regulations identified initial year industry regulatory costs that exceeded $50 million. This SRIA includes both the medicinal and recreational market; consequently, we expect increased direct costs to all cannabis manufacturers will be well over the $50 million threshold for a major regulation.
5. Description of the agency's baseline:
This SRIA compares a hypothetical "legalization and partial regulation" future to a hypothetical future with "legalization and full regulations" for cannabis concentrates, edible cannabis products, and topical cannabis products in each of the three identified markets - medicinal, adult-use, and unlicensed. Manufacturer sales summed across the concentrates, edibles, and topicals markets and across the medicinal and unlicensed segments totals $611 million in 2017 (there was no legal adult-use at the time). After the adult-use market is formed, and after all non-Department regulations are applied, such as the cultivation tax, simulations show that the sum of all manufacturer sales rise to $960 million. Once the Department regulations are applied, the simulation shows that the sum of manufactured cannabis sales across all markets and across the adult-use, medical, and unlicensed segments rises to $1,047 million or about $1 billion.

6. For each alternative that the agency considered (including those provided by the public or another governmental agency), please describe:
   a. All costs and all benefits of the alternative
   b. The reason for rejecting alternative
Benefits and costs are measured in terms of changes in consumer surplus. The first alternative considered imprinting a warning label to the manufactured product itself, in addition to the exterior label. This warning label is applied directly to the surface of the product, either by being marked, stamped, or imprinted. With this approach, we estimate that ongoing annual costs stemming from industry costs of regulation would equal $398 million while ongoing annual benefits stemming from increased demand and reduced risk premium would equal $387 million. This alternative was rejected because it was cost ineffective. Instead we choose a printed label that accompanies any cannabis product. A second alternative is to require Live Scan background checks for all employees and owners of a cannabis company. We estimate that ongoing annual costs stemming from industry costs of regulation equal $322 million while ongoing annual benefits stemming from reduced risk premium equal $317 million. This alternative was rejected because it cost more to achieve the same benefits. We choose the statutory requirement that only the owners of a company need to have a Live Scan background check.

7. A description of the methods by which the agency sought public input. (Please include documentation of that public outreach).
The Department conducted several pre-regulatory stakeholders meetings in various locations throughout the state to provide the public with an opportunity to participate in discussions on specific topics regarding cannabis dispensaries, distributors, manufacturers, testing laboratories, and transporters. Members of the economic team conducting the SRIA solicited input from stakeholders and conducted surveys of the industry. Additionally, the MCRSA SRIA was available for public comment during the spring of 2017.

8. A description of the economic impact method and approach (including the underlying assumptions the agency used and the rationale and basis for those assumptions).
The approach was to determine how proposed regulations affect prices in the manufactured medicinal and adult-use cannabis markets. Price changes stem from increased regulatory costs and decreases in the risk premium. We used those price changes in our model of demand in medicinal, adult-use, and unlicensed markets in order to determine quantity changes in each market. In addition to the costs specified above, we describe other cost and market impacts of the regulations, and we divide them into supply and demand side effects. With combined changes in the medicinal, adult-use, and unlicensed markets, we customized the Impact Analysis for Planning (IMPLAN) Pro software to determine the impact on California Gross State Product and jobs. We also use the price and quantity changes to quantify consumer benefits in terms of changes in consumer surplus, the costs and benefits from the proposed regulations, and alternatives.

Agency Signature: [Signature]
Date: March 27, 2018
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