

# **California Department of Insurance**

# Guidance SB 1120:1

# Use of Artificial Intelligence, Algorithms and Other Software Tools in Utilization Management

# May 5, 2025

The California Department of Insurance (CDI) issues this guidance<sup>1</sup> regarding the requirements set forth under California Insurance Code (CIC) section 10123.135(j).

## Background

Senate Bill 1120 (Becker), (Stats.2024, ch. 879, § 2), in part, added subdivision (j) to CIC section 10123.135. Subdivision (j) provides standards for the use of artificial intelligence (AI), algorithms or other software (hereinafter, decision support tools) in utilization review and management by health insurers and their contracted entities.<sup>2</sup> Section 10123.135(j)(1)(E) provides that the use of these tools shall not directly or indirectly discriminate against insureds in violation of state or federal law. Section 10123.135(j)(1)(F) further provides that these decision support tools are to be applied fairly and equitably, and in a manner consistent with applicable regulations and guidance issued by the federal Department of Health and Human Services (HHS). The federal regulations adopted pursuant to Section 1557 of the Affordable Care Act (ACA) (42 USC section 18116) also establish nondiscrimination requirements applicable to decision support tools.

# Authority

Pursuant to CIC section 10123.135(j)(5), CDI is tasked with developing guidance to promote insurer compliance with federal regulations and guidance regarding the use of decision support tools within one year following the adoption of applicable federal regulations and guidance.<sup>3</sup> The regulations under ACA Section 1557 were published May 6, 2024, with an effective date of July 5, 2024 and later implementation dates

 $<sup>^1</sup>$  This guidance is issued pursuant to CIC § 10123.135(j)(5). Citations are to the California Insurance Code (CIC), unless otherwise noted.

<sup>&</sup>lt;sup>2</sup> SB 1120 also added subdivision (k) to section 10123.135. Subdivision (k) clarifies that health insurers shall not be defined as health care providers.

<sup>&</sup>lt;sup>3</sup> CIC § 10123.135(j)(5).

specified for certain provisions. This guidance is not subject to the Administrative Procedures Act (Government Code section 11340, *et seq*.)<sup>4</sup>

## Applicability

CIC section 10123.135(j) applies to health insurers, their contracted entities, and any other entities through which they engage in utilization review or management, including prospective, retrospective and concurrent review (hereinafter, health insurers and contracted entities).

ACA Section 1557 applies to all operations of an entity principally engaged in health care programs and activities, any part of which directly or indirectly receives federal financial assistance.<sup>5</sup> Health care programs and activities include providing or administering health insurance or other health-related coverage and providing assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage.<sup>6</sup> Entities that meet these requirements are called "covered entities."

### **Information Standards**

CIC section 10123.135(j) provides standards to ensure that insurers and contracted entities using decision support tools in utilization review and management base their review on specified information that is applied in an equitable, nondiscriminatory manner and does not supplant health care provider decision making, including determinations of medical necessity.

Specifically, the decision support tool must base its decision, as applicable, on:

- The insured's medical or other clinical history;
- Individual clinical circumstances presented by the requesting provider;
- Other relevant clinical information in the insured's medical or other clinical record.<sup>7</sup>

<sup>&</sup>lt;sup>4</sup> CIC § 10123.135(j)(5).

<sup>&</sup>lt;sup>5</sup> 45 CFR § 92.2. Federal financial assistance is defined broadly and specifically includes advance payments of the premium tax credit and cost-sharing reduction payments through health care exchanges, including Covered California, established under Title I of the ACA, and payments, subsidies, or other funds extended by the U.S. Department of Health and Human Services (HHS) to any health insurance provider for payment to, or on behalf of, a person obtaining health insurance coverage from that insurer or extended directly by HHS to such person for payment to any entity providing health insurance coverage. 45 CFR § 94.4, see also, 45 CFR § 92.207.

<sup>&</sup>lt;sup>6</sup> 45 CFR § 94.4.

<sup>&</sup>lt;sup>7</sup> CIC § 10123.135(j)(1)(A).

The decision support tool shall not deny, delay, or modify health care services based on medical necessity.<sup>8</sup> A determination of medical necessity shall be made only by a licensed physician or licensed health care professional competent to evaluate the specific clinical issues involved in the health care service requested by the provider.<sup>9</sup>

#### **Prohibited Practices**

A health insurer or contractor shall ensure that:

- the decision support tool does not:
  - Base its determination solely on a group dataset;<sup>10</sup>
  - Supplant health care provider decision making;<sup>11</sup>
  - Directly or indirectly cause harm to the insured.<sup>12</sup>
- the use of the decision support tool does not discriminate against insureds, directly or indirectly, in violation of state or federal law.<sup>13</sup>
- patient data is not used beyond its intended and stated purpose, consistent with the Confidentiality of Medical Information Act (CMIA)<sup>14</sup>, HIPAA<sup>15</sup>, and other applicable laws, including the Insurance Information and Privacy Protection Act (IIPPA).<sup>16</sup>
- the decision support tool shall not deny, delay, or modify health care services based, in whole or in part, on medical necessity.<sup>17</sup>
- determinations of medical necessity shall be made only by a licensed physician or licensed health care professional competent to evaluate the specific clinical issues involved in the health care services requested by the provider.<sup>18</sup>

### **Required Practices**

Health insurers and their contracted entities must:

 ensure that the decision support tools are open to CDI inspection for audit or compliance reviews.<sup>19</sup>

<sup>13</sup> CIC § 10123.135(j)(1)(E).

<sup>16</sup> CIC § 791, *et seq.* 

- <sup>18</sup> CIC § 10123.135(j)(2).
- <sup>19</sup> CIC § 10123.135(j)(1)(G).

<sup>&</sup>lt;sup>8</sup> CIC § 10123.135(j)(2).

<sup>&</sup>lt;sup>9</sup> CIC § 10123.135(j)(2).

<sup>&</sup>lt;sup>10</sup> CIC § 10123.135(j)(1)(B).

<sup>&</sup>lt;sup>11</sup> CIC § 10123.135(j)(1)(D).

<sup>&</sup>lt;sup>12</sup> CIC § 10123.135(j)(1)(K).

<sup>&</sup>lt;sup>14</sup> CIC § 10123.135(j)(1)(J); Cal. Civ. Code § 56.10.

<sup>&</sup>lt;sup>15</sup> CIC § 10123.135(j)(1)(J); Public Law 104-191.

<sup>17</sup> CIC § 10123.135(j)(2).

- include written disclosures pertaining to the use and oversight of decision support tools in the policies and procedures for utilization review and management required by subsection (b) of CIC section 10123.135.<sup>20</sup>
- periodically review the decision support tool's performance, use, and outcomes to maximize accountability and reliability.<sup>21</sup>

#### Compliance with Other Laws: ACA Section 1557

As mentioned above, the decision support tools' criteria and guidelines must comply with this chapter and applicable state or federal law.<sup>22</sup> The decision support tool must be fairly and equitably applied, including in compliance with regulations and guidance issued by the U.S. Department of Health and Human Services (HHS).<sup>23</sup>

On May 6, 2024, the HHS Office for Civil Rights issued regulations implementing ACA Section 1557. HHS specifically addresses automated patient care decision support tools in its regulations. The regulations at 45 CFR section 92.210 clarify that the antidiscrimination protections set forth in ACA Section 1557 apply to "patient care support decision making tools."

The Section 1557 regulations define patient care decision support tool as any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities.<sup>24</sup> In the preamble to the final rule, HHS confirms that patient care decision support tools include automated decision support systems and AI, utilization management applications and related tools for utilization management review, as well as tools used for prior authorization and medical necessity analysis.<sup>25</sup> Therefore, the requirements set forth in 45 CFR section 92.210 apply to decision support tools under CIC section 10123.135(j).

HHS's Section 1557 regulations prohibit discrimination based on race, color, national origin, sex, age, and disability in the use of patient decision support tools and require ongoing identification and mitigation of the risk of discrimination in the use of such tools.<sup>26</sup>

<sup>&</sup>lt;sup>20</sup> CIC § 10123.135(j)(1)(H).

<sup>&</sup>lt;sup>21</sup> CIC § 10123.135(j)(1)(I).

<sup>&</sup>lt;sup>22</sup> CIC § 10123.135(j)(1)(C).

<sup>&</sup>lt;sup>23</sup> CIC § 10123.135(j)(1)(F).

<sup>&</sup>lt;sup>24</sup> 45 CFR § 92.4. The preamble to the proposed rule further clarifies that "types of patient care decision support tools subject to § 92.210 include automated decision systems and AI used to support clinical decision-making." <u>Federal Register: Nondiscrimination in Health Programs and Activities</u> 89 Fed. Reg. (FR) 37522 at 37643 (May 6, 2024).

<sup>&</sup>lt;sup>25</sup> 89 FR 37522 at 37644 (May 6, 2024).

<sup>&</sup>lt;sup>26</sup> 45 CFR § 92.210.

#### **Other Considerations**

To the extent a health insurer or their contracted entity is a "covered entity," they must, on an ongoing basis, identify and mitigate the risk of discrimination from their use of decision support tools to comply with federal requirements under ACA Section 1557.<sup>27</sup> Nothing prohibits a health insurer or their contracted entities that are not covered entities from complying with these requirements.

For further information, contact Stesha Hodges, Assistant Chief Counsel, Health Equity and Access Office, (916) 492-3544, <u>stesha.hodges@insurance.ca.gov</u>.

<sup>&</sup>lt;sup>27</sup> 45 CFR § 92.210.