The use of computer algorithms by Cigna to quickly deny over 300,000 claims in two months, with medical professionals spending only about 1.2 seconds per case based on the algorithm's primary evaluation, has significant implications for patient care:

### 1. Increased Risk of Denied Necessary Care

When claims are denied based on algorithms without thorough human review, there is a high risk that legitimate claims for necessary medical care could be unjustly denied. This can result in patients being unable to access or afford essential treatments, medications, surgeries, or diagnostic tests. Denied claims may delay critical care, leading to worsening health conditions, preventable complications, or even life-threatening situations.

# 2. Erosion of Patient Trust in Healthcare Systems

Patients expect that decisions about their healthcare, especially those involving insurance coverage, are made carefully, thoughtfully, and fairly. Knowing that claims are being processed with minimal human oversight can erode trust in the healthcare system. Patients may feel that decisions are driven more by cost-cutting and profit maximization than by medical necessity and patient welfare. This loss of trust can discourage patients from seeking needed care or from following prescribed treatment plans.

# 3. Compromised Quality of Care

The use of algorithms that rely on historical data and set criteria may not account for the complexities and nuances of individual patient cases. Medical decisions often require consideration of a patient's unique medical history, comorbidities, lifestyle, and other contextual factors that an algorithm may overlook. This one-size-fits-all approach can result in inappropriate or suboptimal care recommendations, ultimately compromising the quality of patient care.

# 4. Disproportionate Impact on Vulnerable Populations

Patients from marginalized or vulnerable groups (such as low-income individuals, people of color, the elderly, or those with complex medical conditions) may be disproportionately affected by automated claim denials. These populations are more likely to face barriers in challenging denials, understanding the appeals process, or accessing alternative resources, potentially exacerbating existing health disparities.

# 5. Increased Administrative Burden on Patients and Providers

When claims are denied en masse by algorithms, patients and healthcare providers often face a significant administrative burden to appeal these denials. The appeals process can be time-consuming, stressful, and costly, potentially deterring patients from pursuing necessary care. This can also strain healthcare providers, who may need to spend considerable time and resources on paperwork and justifications to get claims approved, diverting attention away from direct patient care.

#### 6. Psychological and Emotional Stress for Patients

Receiving a claim denial, especially when it is for a treatment or service deemed medically necessary, can cause significant anxiety, frustration, and stress for patients. This stress is compounded when patients feel that their cases have not received the individualized attention they deserve. The emotional burden can affect patients' overall well-being and adherence to treatment plans, potentially impacting their recovery or health outcomes.

#### 7. Potential for Misdiagnosis or Delay in Diagnosing Conditions

If insurance denials based on algorithms prevent or delay diagnostic tests or specialist referrals, there is a risk that serious conditions may go undiagnosed or be diagnosed late. Timely diagnosis is critical in managing many health conditions effectively, and delays can lead to more severe health issues, requiring more intensive and costly interventions later on.

#### 8. Lack of Recourse and Transparency

The reliance on algorithms for claims evaluation creates a lack of transparency regarding the criteria used to deny claims. Patients and providers may find it challenging to understand why a claim was denied and what steps can be taken to rectify the situation. This lack of transparency can lead to confusion, dissatisfaction, and limited recourse for patients who feel their care is being unjustly restricted.

#### 9. Ethical and Legal Concerns

The approach used by Cigna raises serious ethical and legal concerns about whether the company is complying with regulations that require individualized medical assessments for claims. If AI is being used to circumvent these requirements, it could lead to regulatory action, legal challenges, or financial penalties. Such practices could also damage the insurer's reputation, further eroding public confidence in their commitment to fair and ethical practices.

#### 10. Potential Undermining of Medical Professional Judgment

By allowing algorithms to make preliminary decisions that heavily influence claim outcomes, the role of medical professionals is reduced to merely validating the algorithm's decision rather than making an independent assessment. This can undermine the professional judgment and expertise of healthcare providers, potentially leading to decisions that prioritize efficiency over patient-centered care.

#### In Summary:

Relying heavily on algorithms and allowing minimal human oversight in claims evaluation can significantly harm patient care by leading to unjust denials of necessary care, undermining trust, compromising quality, and disproportionately affecting vulnerable populations. It creates barriers to care, increases administrative burdens, and raises ethical, legal, and transparency concerns, all of which ultimately impact patient outcomes and overall health equity.

Here are some specific examples illustrating the potential impacts of Cigna's use of algorithms for rapid claim denials:

# 1. Increased Risk of Denied Necessary Care

• Example: A patient with a history of heart disease needs a stress test to evaluate chest pain. The algorithm, trained on average data, deems the test unnecessary because the patient's overall risk profile appears low based on generic criteria. However, without a human medical professional reviewing the patient's full history, the algorithm misses key details—like a previous heart attack—that make the test critical. As a result, the test is denied, delaying a potentially life-saving diagnosis.

## 2. Erosion of Patient Trust in Healthcare Systems

• Example: A diabetic patient receives a denial for a new continuous glucose monitor (CGM) that their doctor prescribed due to frequent hypoglycemia. The algorithm flags it as unnecessary based on outdated guidelines or incomplete data, without considering the patient's specific circumstances. The patient, already struggling with their condition, loses trust in both the insurer and the healthcare system, feeling that cost-cutting measures are prioritized over their safety and well-being.

### 3. Compromised Quality of Care

• Example: An elderly patient with multiple chronic conditions (like hypertension, diabetes, and arthritis) is prescribed a complex medication regimen tailored to manage all these conditions. The algorithm evaluates each medication separately and denies coverage for one medication that it deems redundant. However, the medication is essential for balancing the effects of the other drugs. This denial could disrupt the patient's treatment plan, leading to poorly controlled symptoms and increased risk of complications.

# 4. Disproportionate Impact on Vulnerable Populations

• Example: A low-income patient with mental health issues is prescribed a specific form of therapy by their psychiatrist. The algorithm, which might be biased towards cheaper, standardized treatments, denies the claim for the specific therapy without considering the patient's unique needs or history of failed treatments. The patient, who lacks the resources to appeal or pay out-of-pocket, may forgo the therapy, exacerbating their mental health condition.

### 5. Increased Administrative Burden on Patients and Providers

• Example: A cancer patient undergoing chemotherapy has a claim for a necessary antinausea medication denied. The patient's oncologist spends hours gathering documentation, filling out forms, and making phone calls to appeal the denial. This time-

consuming process diverts valuable time away from other patients and can delay the patient's access to the needed medication, increasing their suffering.

#### 6. Psychological and Emotional Stress for Patients

• Example: A patient who recently underwent surgery to remove a tumor receives a notification that their claim for post-operative physical therapy has been denied by an algorithm. The sudden denial adds to their emotional distress and anxiety about their recovery, causing them to worry about their financial situation and long-term health. This additional stress negatively impacts their recovery process.

#### 7. Potential for Misdiagnosis or Delay in Diagnosing Conditions

• Example: A young woman experiencing severe abdominal pain is denied coverage for a CT scan, as the algorithm considers her symptoms as non-specific and low-risk based on population data. However, a human reviewer might have noted other subtle symptoms indicating the possibility of appendicitis or another serious condition. The denial delays the diagnosis, leading to a ruptured appendix and emergency surgery that could have been avoided with timely intervention.

#### 8. Lack of Recourse and Transparency

• Example: A patient with rare genetic disease is denied coverage for an expensive, specialized treatment that only a few hospitals offer. The denial notice gives little explanation beyond "not medically necessary," leaving the patient and their family confused about the criteria used. They struggle to navigate the opaque appeals process, losing precious time that could be used for treatment.

### 9. Ethical and Legal Concerns

• Example: A whistleblower reveals that Cigna's algorithm routinely denies claims for a commonly used but costly cancer drug, regardless of patient-specific medical records, to save on costs. This practice violates laws that require individualized medical assessments. A lawsuit is filed by patients and advocacy groups, alleging that Cigna prioritized profits over patient care, resulting in harm to thousands of patients.

#### 10. Potential Undermining of Medical Professional Judgment

• Example: A pediatrician submits a claim for a specialized formula for an infant with severe allergies and gastrointestinal issues. The algorithm denies the claim based on the assumption that standard formulas are sufficient for most cases. The pediatrician's clinical judgment, which takes into account the infant's unique medical needs and allergic reactions, is undermined, and they are forced to either appeal or prescribe a less suitable formula that could risk the infant's health.

#### In Summary:

These examples demonstrate how relying on algorithms for rapid claims processing can lead to denied necessary care, compromised quality of care, and increased stress and burden on patients and providers. Vulnerable populations may be disproportionately affected, and the lack of transparency and human oversight in these decisions can result in significant ethical, legal, and healthcare challenges.

To address the challenges and risks associated with the increased use of artificial intelligence (AI) in health insurance and healthcare, a comprehensive legislative and regulatory framework should be enacted. This framework should prioritize individualized patient assessments, human accountability, and ethical use of AI technology. Here are some key components that should be included:

#### 1. Mandatory Human Oversight

- **Human-in-the-Loop Requirement**: Laws should require that AI tools are used as decision-support systems, not as the final decision-makers. Every decision affecting patient care or health insurance coverage should involve a human professional who reviews and approves the decision, particularly when it involves denying care or coverage.
- Human Review Right: Patients should have the right to request a human review of any decision made with the assistance of AI. This is especially important for denials of treatment, medication, or services.

#### 2. Transparency and Explainability Standards

- Explainability Requirements: Regulations should require that AI systems provide clear, understandable explanations for their recommendations or decisions. Patients and healthcare professionals should have access to information on how an AI decision was made, including the data sources and criteria used.
- **Disclosure Obligations**: Health insurers and providers should disclose when AI is being used in decision-making processes. Patients should be informed about the role of AI in determining their care or coverage and what specific data is being analyzed.

#### 3. Data Privacy and Security Protections

- Enhanced Data Protection Laws: Regulations should enforce strict standards for data privacy and security, especially for personal health information (PHI). Compliance with existing data protection laws like HIPAA (in the U.S.) or GDPR (in the EU) should be mandatory, and additional protections may be necessary to address the specific challenges posed by AI.
- Anonymization and De-identification Standards: Data used by AI systems should be anonymized or de-identified to protect patient privacy, except when personally identifiable information is necessary for specific, legitimate purposes such as personalized treatment planning.

#### 4. Bias Mitigation and Fairness Requirements

Bias Audits and Reporting: AI tools should undergo regular, independent audits to
detect and mitigate biases that could lead to discriminatory outcomes based on race,
gender, age, socioeconomic status, or other factors. These audits should be publicly
reported to ensure accountability.

• Equity Standards: Legislation should require that AI systems are designed, trained, and deployed to adhere to equity standards, ensuring that all patients receive fair treatment and that AI does not reinforce or exacerbate existing health disparities.

# 5. Regulatory Oversight and Certification

- Pre-Market Evaluation and Certification: AI tools used in healthcare and health insurance should be subject to regulatory review and certification before they are deployed. This could be modeled on the FDA's pre-market approval process for medical devices.
- Ongoing Monitoring and Auditing: AI systems should undergo continuous monitoring to ensure they remain safe, effective, and unbiased over time. Regulatory bodies could require regular performance audits and updates to maintain certification.

### 6. Accountability and Liability

- Clear Accountability Frameworks: Regulations should establish who is accountable when AI-assisted decisions harm patients, whether it's the healthcare provider, insurer, or AI developer. This helps ensure that entities deploying AI tools are responsible for their consequences, fostering ethical behavior.
- **Defined Liability Pathways**: Laws should clearly define liability in cases where AI errors result in harm, including penalties for non-compliance or negligence.

# 7. Patient Rights and Appeals Processes

- Strengthened Appeals Processes: Laws should ensure patients have the right to a fair and transparent appeals process for any decision made with AI involvement. This process should include timely human review and resolution.
- Right to Explanation and Recourse: Patients should have a right to understand the basis for AI-driven decisions and be provided with clear pathways for challenging or appealing those decisions.

# 8. Ethical Guidelines for AI Development and Use

- Ethical Standards for AI: Developers of AI tools should be required to adhere to ethical guidelines that prioritize patient safety, informed consent, and fairness. These standards should include commitments to transparency, privacy, and non-discrimination.
- Informed Consent Requirements: Patients should provide informed consent for the use of AI in their care, understanding what it entails, its benefits, limitations, and potential risks.

# 9. Education and Training

• Training for Healthcare Professionals: Healthcare providers and insurers should be required to train staff on the use of AI tools, including understanding their limitations, biases, and appropriate use in clinical and administrative settings.

• Public Awareness Initiatives: Public awareness campaigns should inform patients about the use of AI in healthcare, including how it may impact their care and their rights under the law.

#### 10. Periodic Review and Adaptation of Laws

• **Dynamic Regulation Framework**: Laws and regulations should include mechanisms for regular review and updates to keep pace with the rapid evolution of AI technologies and their applications in healthcare. This flexibility ensures that the regulatory environment can adapt to new risks and opportunities as they arise.

#### 11. Promoting Innovation Within Safe Boundaries

- Innovation Encouragement: Encourage the development and use of AI in healthcare by providing a clear legal framework that reduces uncertainty for innovators while maintaining high safety, ethical, and fairness standards.
- Public-Private Partnerships: Encourage collaboration between public institutions and private sector companies to establish standards, share best practices, and foster innovation in a way that benefits patient care and maintains public trust.

#### Why This Framework is Important:

Such a framework is essential to balance the potential benefits of AI in healthcare and insurance—such as increased efficiency, accuracy, and personalized care—with the need to protect patient rights, ensure safety, and maintain trust in healthcare systems. By ensuring that AI systems are transparent, accountable, and used ethically, we can harness their power to improve healthcare while safeguarding the rights and well-being of patients.