

## Establishing Artificial Intelligence Compliance Systems in Dermatology Private Practice

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Received: 05 Mar 2026; Accepted: 15 Mar 2026; Published: 25 Mar 2026

**Citation:** Liana N Ly. Establishing Artificial Intelligence Compliance Systems in Dermatology Private Practice. AJMCRR. 2026; 5(3): 1-11.

### Abstract

*The integration of artificial intelligence (AI) tools into dermatology private practice introduces new dimensions of diagnostic support, workflow efficiency, and patient engagement, yet also demands rigorous compliance infrastructure to mitigate legal, ethical, and operational risk. Establishing an AI compliance system within a private dermatologic setting requires the development of a multidisciplinary oversight process encompassing algorithm validation, data governance, cybersecurity, and adherence to emerging regulatory standards such as the EU AI Act, U.S. FDA guidelines on Software as a Medical Device (SaMD), and state-level privacy legislation like the California Consumer Privacy Act (CCPA). Risk stratification of AI tools used for triaging skin lesions, generating differential diagnoses, or automating clinical documentation must be based on their functional classification (assistive vs. autonomous), intended use, and data origin. Practices must implement thorough consent protocols for the use of patient data in AI training or real-time decision support, ensuring transparency in model limitations, explainability, and the delineation of clinical accountability. Vendor contracts should include audit rights, data use limitations, and indemnification clauses to safeguard against liability stemming from algorithmic error or patient harm. Internal policies must define clear documentation standards for AI-assisted clinical decisions and incorporate human-in-the-loop review mechanisms to prevent overreliance on algorithmic outputs. Periodic auditing of AI tool performance, bias monitoring across skin types and demographic variables, and alignment with dermatology-specific clinical quality measures are necessary to ensure regulatory conformity and equitable care delivery. Staff training programs should incorporate technical tool use, regulatory literacy, ethical implications, and protocol escalation pathways in cases of*

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*AI malfunction or disagreement with clinical judgment. A well-structured AI compliance system in dermatology private practice serves not only to fulfill legal obligations, but to uphold standards of clinical safety, transparency, and patient trust as algorithmic technologies become integrated into the routine administration of dermatologic care.*

**Keywords:** artificial intelligence, compliance system, cybersecurity, dermatology.

## Introduction

The potential utilization of artificial intelligence (AI) in healthcare practices has garnered interest from medical personnel and patients alike. AI-driven algorithms not only assist clinicians with decision-making and documentation, but can also improve public health by identifying at-risk patient populations, reducing healthcare costs, and improving healthcare access (1)(2). Prospective applications of AI in dermatology have been of particular interest, largely due to the specialty's heavy dependence on visual pattern recognition and a shortage of dermatologists in the United States (3)(4). However, AI is a double-edged sword, as overreliance may compromise both clinician and patient judgement. For example, smart technologies have promoted self-diagnosis through accessibility. Wongvibulsin et al. (2024) characterized direct-to-consumer (DTC) dermatology mobile applications utilizing AI to facilitate early detection or self-monitoring of skin lesions (5); this analysis depicted lack of transparency in specific AI algorithms, insufficient or non-disclosed safeguards for data privacy, and limited regulatory oversight with absence of U.S. Food and Drug Administration (FDA) approval. In our current healthcare landscape, dermatologists have shown interest in integration of smart technologies into their practices (6), yet rely primarily on their own clinical-decision making (7). This suggests that while AI is garnering attention and trust from patients and physicians alike, its adoption into workflows must be met by comprehensive frameworks to preserve

clinical integrity. As a result, compliance systems are essential to support responsible integration of machine intelligence into dermatology practices.

Compliance systems are structured frameworks designed to ensure that artificial intelligence technologies are implemented in accordance with legal, ethical, operational, and clinical standards. In high-volume dermatology private practices, they empower dermatologists, office staff, and patients to leverage the benefits of AI while simultaneously mitigating associated risks. Several steps are required to protect the practice from such legal risks. Dermatology private practice practitioners should delineate the role of vendors as stakeholders in the creation of AI systems (8). Compliance infrastructure should help practices align with both federal regulatory standards and state-level legislation. In addition, the framework should stratify AI tools based on their intended uses, training datasets, and functional capabilities. Unfortunately, currently available models are trained using datasets lacking representation of skin-of-color patients, leading to inextricable biases that may cause suboptimal patient care (9). To protect patients, compliance systems ensure continued AI quality assurance through audits and bias monitoring, transparent documentation, and cybersecurity protocols. Lastly, compliance system infrastructure should implement continued staff education (8), particularly in situations when AI-assisted decisions may contradict human judgement.

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Although implementing such systems may be time and resource-intensive, particularly for smaller practices, they offer non-negotiable benefits: promotion of patient trust, reduction of algorithmic bias, and increased physician confidence in AI adoption (10). All aspects of an AI compliance system are mandatory to proper assimilation and maintenance of AI into dermatology private practices. Extensive literature has explored both the potential applications of AI-driven algorithms and the ethical, legal, and functional barriers to further adoption; however, there is a current paucity of guidance on how to navigate these issues. This review details a comprehensive framework for successful implementation of AI into dermatology private practices, equipping dermatologists with the necessary knowledge to maximize clinic efficiency, patient outcomes, and patient satisfaction while protecting against legal, ethical, and operational risks.

## Review

With the rapid and widespread adoption of AI, governance at both federal and state levels is essential for individual data protection. On a global scale, European legislators published the Artificial Intelligence Act (AI Act) in July 2024, which was enforced the following months with full applicability anticipated in August 2027. This act is expected to set standards beyond AI products in Europe, providing policy recommendations that keep patient protection at the frontline of AI integration (11). The risks posed by the health-related AI system will determine the stringency and obligations of both the provider and deployer. In the United States, the Food and Drug Administration (FDA) regulates medical devices based on a risk-based classification system in the guidelines on Software as a Medical Device (SaMD). Medical software

without hardware components is regulated based on the healthcare condition and the significance of the SaMD information in clinical decision-making (12). At the state-level regulation, the California Consumer Privacy Act of 2018 (CCPA), for example, is specifically centered around consumer data protection and personal autonomy over patients' medical data (13). Though these various governing laws all involve patient protection at the core, there are differences in the coverage of AI regulation, with gaps in the setting of health care. It is evident that with the new and rapidly innovative applicable features of AI, there is an increasingly necessary need for a multifaceted and dynamically evolving process for regulation of patient data and ethical use, especially in the context of healthcare, that does not yet exist.

These regulations are central to the practical integration of AI in dermatology private practices. Factors that have hindered the clinical utilization of AI advancements include imbalances between data accessibility and patient privacy, medical-legal challenges, and algorithmic fairness (14). Absence of clear guidelines in patient privacy, data storage, and data integration into the existing electronic health record systems complicates standardization of AI compliance within dermatology private practices (15). Furthermore, differing data privacy laws can alter execution of clinical trials by location (13), limiting external validity and weakening AI algorithms for dermatology clinic use. Given the lack of central secure storage systems for patient information in smart technologies, private practices should rely on applicable federal and state guidelines, including HIPAA, as templates for operations.

Beyond regulatory guidelines, enhancing dermatol-

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ogy practices with intelligent systems involves navigating relationships with vendors. The integration of external vendors offering artificial intelligence-driven support tools into dermatology clinic workflows requires proper oversight and exhaustive contractual frameworks. Vendors play a critical role in development and maintenance of technology systems that support clinical decisions; therefore, their operations must uphold patient safety and healthcare regulations. Previously, healthcare information technologies (HIT) vendors have included indemnification clauses in contracts to avoid malpractice or personal injury responsibility. This practice raised ethical issues, prompting recommendation from the Task Force to prioritize patient safety, transparency, and accountability over legal absolution (16). With the increasing adoption of AI in HIT, this issue has grown more complex and divisive. Cestonaro et al. (2023) depicts varying views on medical liability; some believe that vendors should be held liable when AI systems are used as intended, but clinicians may still be held liable when using assistive AI outputs. In contrast, vendors may hold responsibility for the use of autonomous AI by non-specialist providers (17). Failure to secure these contractual elements could expose clinics to compliance violations and harm patients; dermatology private practices must closely work with vendors to create contracts nuancing intended uses, potential risks, and proper reporting of adverse events.

To further mitigate liability and preserve patient trust, dermatology practices should implement detailed informed consent protocols (ICP). They should extensively define the scope of AI usage as well as disclose how patient data may be used for AI training and real-time decision support. In a scoping review studying patient perspectives re-

garding AI usage, Osnat discovered that while over 75% of patients expressed notable benefits and utility of AI in healthcare, approximately 50%-70% of patients also expressed concern about ethical use, privacy risks, patient safety, autonomy, and trust (18). The “black box” phenomenon, which refers to the lack of transparency in many AI systems, may limit patient trust. Because of AI’s hidden decision-making process, patients may feel less empowered to accept AI-driven algorithms. To best address these concerns, dermatologists should use both verbal and written communication to approach informed consent for AI usage. Furthermore, consent forms should be written in plain language and should clearly outline ethical and legal considerations (19). Well-structured ICPs that thoroughly document AI contributions will improve both patient trust in intelligent technologies and their clinicians.

ICPs should be specifically tailored by the type of AI employed, properly educating patients about assistive and autonomous functions. The distinction between assistive and autonomous AI systems is essential to risk stratification. Assistive AI is designed to aid clinicians by providing suggestions, identifying potential concerns, or streamlining data, without making decisions on their own. This is the foundational goal of medical AI: to aid in diagnosis, treatment planning, and outcome prediction (20). These AI tools are less risk-prone because they depend on human input to execute. Assistive systems enhance clinician performance by collecting and analyzing data, executing tasks under supervision, or adapting to tasks through guidance (2). For example, a decision-support AI system interpreting dermoscopic images and marking unusual lesions leaves the final diagnostic choice to the clinician (22). In contrast, autonomous AI operates

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with little or no human intervention. Autonomous AI can independently make decisions or recommendations (21). These systems respond to real-world conditions and are able to perform actions. Autonomous AI systems can triage skin lesions submitted via teledermatology apps and generate differential diagnoses without clinician review (23). They can also appear in clinical settings, like stand-alone implanted devices, or in admin operations, like computerized receptionists processing patient registration (21). Autonomous AI is well-suited to provide higher efficiency and accessibility, notably in large-volume practices, but comes with severe challenges. Due to the outsourcing of clinical judgment to these models, there are severe regulatory, ethical and liability issues. An understanding of these AI classification differences is critical for dermatology practices.

Under experimental settings, autonomous AI within dermatology has shown promising results. Esteva et al. (2017) demonstrated that a deep learning algorithm could match the diagnostic performance of 21 board-certified dermatologists in diagnosing common and deadly skin cancers (3)(24). Since then, further studies have found that smart technologies can even outperform groups of experienced dermatologists in lesion classification (3). However, in terms of use for private practices, dermatologists may prefer assistive AI to classify lesions, and flag high-risk features. Dermatologists are receptive to the use of AI systems to diagnose and monitor skin lesions, but continue to value the physician-patient relationship and clinical precision (6). In a cross-sectional study, Nelson et al. (2021) reported that 76% of dermatologists would be more likely to biopsy a lesion with no clinical suspicion of cancer if an AI tool indicated possible malignancy. In contrast, only 8% of dermatologists reported that they

would be less likely to biopsy a clinically suspicious lesion if indicated that it was benign. Furthermore, 74% of clinicians were open to using an AI tool to help monitor skin lesions (6). In the current landscape of dermatology, dermatologists have shown interest in integrating AI tools into their private practices, but will primarily rely on their own clinical-decision making capacities.

Appropriate technical practices and thorough documentation are essential to support the intended functions of AI models by dermatologists and medical staff alike. Ma et al. (2024) proposed that competency in working with AI systems is vital for bias recognition, ethics, and regulatory competence (25). The Association of American Medical Colleges (AAMC) reinforces this perspective in its published principles for ethical and transparent AI use, emphasizing the importance of privacy, transparency, and bias-conscious physician training (26). However, the responsibility to protect patient care and privacy belongs to all personnel staff involved in machine intelligence operations, not merely physicians (27)(28). Support staff should be trained on documentation, regulatory literacy, tool use, and ethical implications. Rincon et al. (2025) introduced NIH's Bridge2AI Training, Recruitment, and Mentoring (TRM) curriculum as an ideal model that allows for ongoing training (29). The cross-disciplinary TRM curriculum consisted of structured mentor-scholar networks, providing customized learning pathways; it succeeded in fostering ethical applications of AI for biomedical purposes (29). Similarly, tailored learning pathways for dermatology medical staff may promote proper AI competencies and support ethical implementation.

In addition to proper staff education, safe and effective AI integration also depends on role-specific

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access to the AI system. In order to prevent misuse and protect sensitive health data, practices must implement a tiered access policy that is specific to each healthcare role. Nelson et al. (2025) emphasized that AI systems should restrict user permission based on roles such as medical assistants, nurses, and physicians (30). In a similar context, Crigger et al. (2019) provided an example: patients can only view their own AI-generated reports; administrators have wide visibility but cannot edit diagnoses; and physicians can review and override AI diagnoses (31). Such role-based access is critical in dermatology clinics, where a variety of personnel—dermatologists, physician assistants, nurse practitioners, medical assistants, front-desk staff, and administrators—collaborate to assist patients.

When establishing artificial intelligence as clinical assistants for dermatology private practices, it is imperative to develop detailed internal protocols to guide human intervention. These policies should set expectations for staff functions during technological malfunctions, conflicts with clinician judgement, and high-uncertainty cases. While some preliminary studies suggest that AI may outperform dermatologists in diagnostic accuracy across several skin conditions, models perform poorly in ambiguous cases such as amelanotic lesions (32). In contrast, hybrid approaches utilizing both human judgement and AI pattern-recognition have produced superior results to both independent human and independent AI findings; less experienced clinicians gain the most from AI-based support (32) (33), furthering its utility in private practices training non-physician dermatology providers. These findings highlight the value of collaborative human-AI workflow, optimizing care delivery across variable levels of clinical training.

“Human-in-the-loop” frameworks embody this hybrid approach by establishing escalation protocols for human verdicts. For AI systems assisting with diagnostic functions, this feature may function by flagging select cases for mandatory practitioner review. A tiered risk categorization may stratify predictions by confidence levels; Chanda et al. (2024) introduced an explainable AI (XAI) methods system that denoted either “strong evidence of characteristic(s)” or “some evidence of characteristic(s)” (34). This nuanced communication and transparency defers responsibility to clinicians and staff members, enhancing trust in the technology systems. Another type of “human-in-the-loop” framework involves mandatory human review for each case, regardless of risk categorization. Systems may also be designed to avoid diagnostic judgement and other clinical functions altogether in ambiguous situations, automatically routing them to medical personnel (35). While this approach may seem counterintuitive to its assistive functions, these “selective prediction” models offer tangible working conditions improving trust in AI. In addition to mitigating immediate risks to patient care, “human-in-the-loop” frameworks may simultaneously monitor and modify AI performance; clinicians reviewing the models’ validity can feed data back into the development algorithm with auditing processes. Including human checks as escalation pathways ensure that dermatologists remain central to the diagnostic process, provide legal protection in cases of near-miss adverse events, and support continued improvement of AI algorithms.

Ensuring continuous improvement of these algorithms require dermatologists to evaluate the biases that currently exist within AI models. Kashish et. al (2025) reports that AI models are trained on datasets that lack substantial representation of images

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from patients with Fitzpatrick skin types IV-VI (36). The lack of Fitzpatrick IV-VI representation in datasets leads to the introduction of bias, causing underperformance by the models when used in people with these skin types. Missed or delayed diagnosis leads to worse outcomes and further exacerbates disparities in healthcare. Another factor that contributes to bias in AI algorithms is the gaps in patient access to dermatologic care, further lending to the lack of representation in datasets used to train the models (37). This highlights an interesting dilemma; though AI models have great potential to help underserved populations, developing and training the systems to properly serve these patient populations is difficult. Label noise is another source of bias for AI models, arising when images used to train the datasets are labeled by visual consensus only without histopathologic confirmation (38). Without histopathologic confirmation, there is more room for bias to be introduced into the dataset, especially with uncommon diseases and atypical manifestations in skin types IV-VI.

Dermatologists must recurrently monitor model outputs for these biases and provide corresponding model updates. Daneshjou et. al (2022) shows that AI models can be retrained with the addition of diverse image sets to help decrease the gap in accuracy in model outputs between those with Fitzpatrick skin types I-II and V-VI (38). This has the potential to strengthen AI models used in dermatology practices, ultimately improving outcomes for patients with Fitzpatrick types IV-VI. Daneshjou et. al (2022) outlined a Checklist for Evaluation of Image-Based Artificial Intelligence (AI) Algorithm Reports in Dermatology (CLEAR Dermatology) (38). The list incorporates the data used to train the model, techniques for labeling of images and development of algorithm, technical assessment of model

performance, and application of model. These guidelines can be used to both initially evaluate and re-evaluate AI models used in dermatology practice. Periodic, life-long auditing of AI models will help to ensure regulatory conformance and equitable healthcare delivery.

As examined throughout our review, establishing artificial intelligence compliance systems for dermatology practices requires meticulous data preparation and validation, a well-structured integration into clinic workflow, scrutiny to protect patients, and compliance to evolving regulatory standards. Physician versus vendor accountability presents another prospective challenge in implementation of AI compliance systems. Determination of liable parties for AI-assisted clinical decisions is largely under debate and highly dependent on the degree of imposed harm (39). To protect both providers and patients, there is a perpetual need to re-evaluate the legalities surrounding such AI systems.

If upheld responsibly, the future of AI in dermatology holds vast opportunities for practice efficiency, equity, and increasing healthcare accessibility. Substantial benefits include enhancing clinical decision making, minimizing bias via more accurate detection of lesions across all skin types, and streamlining patient safety, education and compliance (40) (41). Guaranteeing such benefits requires thorough staff education, data quality management, specialty-wide coding regulations, meticulous consent procedures, and transparency of AI-powered data acquisition and usage. Establishing these aspects of AI compliance systems functions to augment physician-patient trust and empower patients in their own healthcare decisions.

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## Conclusion

Our review highlights the necessity of robust and reliable compliance systems in dermatology clinical practices utilizing artificial intelligence technologies. A comprehensive infrastructure is required to ensure ethical, effective, and safe implementation. Further research exploring standardized implementation structures is essential to establishing patient trust and clinician confidence in AI utilization within dermatology private practices.

**Conflicts of Interest:** None declared.

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