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2024 Healthcare Marketing Compliance Guide

Threats, trends and solutions

Contents

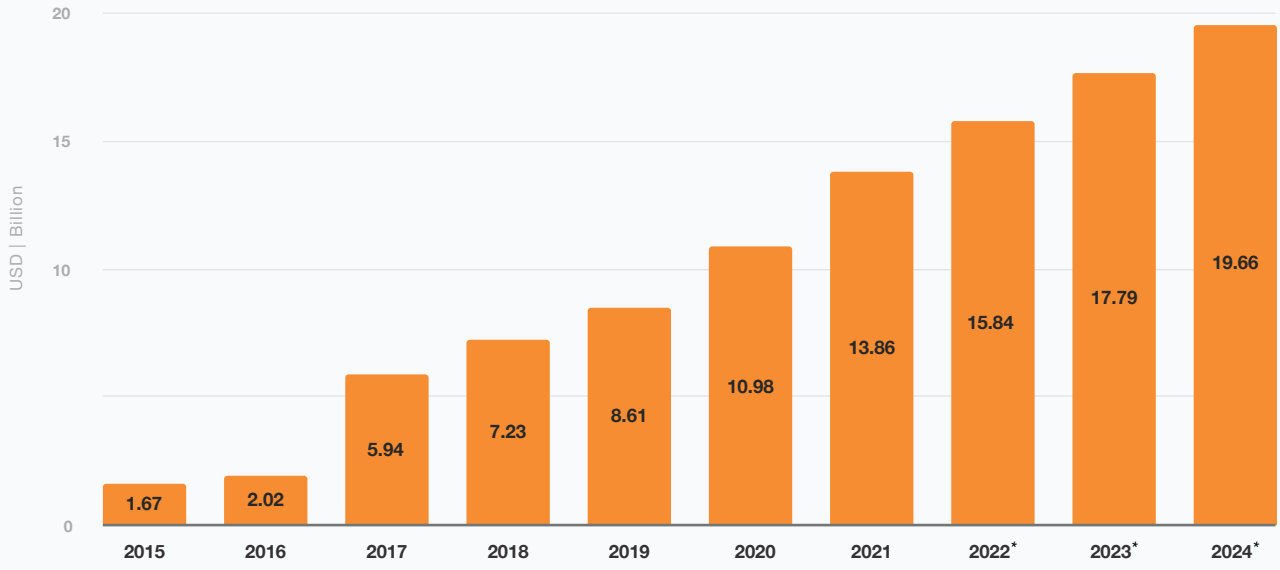
Executive Summary

The surge in healthcare digital ad spend is accompanied by an increasingly complex array of regulatory requirements designed to keep the public safe from misleading claims and inaccurate information. While many marketers believe the economy, tight budgets and dynamic market conditions are the biggest threat to their go-to-market plans, balancing marketing ROI with ever-changing regulations should be a far bigger concern.

Each year, governing bodies issue billions of dollars in penalties for non-compliance. The U.S. Federal Trade Commission, Australian Health Practitioner Regulation Agency and the U.K's Medicines and Healthcare products Regulatory Agency are responsible for many of the guidelines that regulate healthcare services, facilities, medical devices and drugs. However, there are many more governing bodies and considerations that healthcare marketers need to be aware of. Marrying compliance and content demands is no easy feat, and this report exists to help healthcare marketing leaders scale content production while achieving legal and regulatory compliance.

In this guide, you'll find an overview of marketing compliance threats, trends, predictions and solutions that every healthcare marketing leader needs to know.

Healthcare and pharmaceutical industry digital advertising spending in the United States from 2011 to 2024 (in billion U.S. dollars)



Source: Statista.com 2021

**Forecast*

Disclaimer: *This document is not intended as a substitute for legal or regulatory advice. This report has been prepared using both public and private data by IntelligenceBank, a provider of software that helps companies stay on brand and adhere to regulatory compliance. Companies should seek professional legal and regulatory advice when establishing internal compliance protocols.*

9 Critical Healthcare Marketing Compliance Trends & Threats

Marketing regulatory compliance enforcement is designed to keep the public safe from misleading advertising claims, they are diligently enforced in the healthcare sector. Consequences for violations run into the billions.

01

AI Technology used for Compliance and Surveillance: While using AI to create content is commonplace, AI is quickly making the detection of errors just as common. Fewer compliance breaches will go undetected as regulators use AI to monitor digital ads at scale. The UK advertising standards body (ASA) has implemented an active ad monitoring system that uses AI to scan live online ads and flag breaches of the code. The ASA plans to scan 10 million ads for wrongdoing in 2024[1].

02

FTC Cracking Down on Misleading Ad Claims: The economic downturn has led to a trend in people managing their own health to avoid medical bills. As a result, the supplement industry has surged. So too have the claims of misleading advertising upheld by the FTC. In the past ten years, the FTC has initiated 120 lawsuits disputing supplement health claims[2]. In 2023, the FTC put approximately 670 advertisers on notice that they should avoid deceiving consumers with advertisements that make product claims that cannot be backed up or substantiated. Most of the entities were involved in the marketing of OTC drugs, homeopathic products, dietary supplements, or functional foods.

03

U.S. Congress Urges FDA to Enact Stronger Social Media Enforcement. US Senators Richard Durbin and Mike Braun issued a letter to the FDA stressing the importance of updating and enforcing regulations against misleading social media advertisements for prescription drugs[3].

04

Increasing Fees for Marketing Code Violations. Incidents of drug companies suspected of violating the UK's code of practice governing pharmaceuticals have more than tripled in two decades. An ensuing backlog of cases has caused regulators to increase fees associated with complaints by more than 40%[4].

05

Greater Scrutiny on Brand Partnerships: Danish pharma giant Novo Nordisk was recently found to be in contravention of the ABPI code of practice over its sponsorship of weight loss programs promoting its products. It has been suspended from the trade association until 2025[5].

06

AI and Automation is not just for Admin and Patient Outcomes: Many functions and departments within healthcare are being partially automated, and marketing is no exception. Healthcare marketers are moving away from legacy processes to ones that leverage automation and AI to reduce the risk of compliance failures and allow them to scale at the same time.

07

Social Media Endorsements Are Being Closely Monitored: Recent initiatives from regulatory bodies have tightened the rules on transparency between brand partners and with online influencers. In Europe and the UK, pharmaceutical companies are responsible for all social media activities including those by third parties - even if the third party acts beyond the scope of its contract. The FTC has also sent warning letters to two peak industry bodies that may have violated the FTC Act by failing to adequately disclose influencers who were purportedly hired to promote the safety of aspartame or the consumption of products containing sugar. Australia's consumer watchdog the ACCC has found that potentially over 80% of influencers are posting misleading claims[6].

08

Growing Enforcement of Negative Option Marketing. The FTC broadly defines Negative Option Marketing as a practice that assumes no action on the part of the consumer to reject or cancel an agreement equals permission to charge. This applies to the growing trend to charge for ongoing subscription services. The owner of multiple skin care companies, Gopalkrishna Pai, was recently found to have unlawfully charged consumers undisclosed fees for online subscriptions. The total judgment against him is over $34M[7].

09

The National Advertising Division (NAD) Flexes its Muscles on Health Product Advertising Compliance. A recent NAD prescription drug case signals the re-emerging interest of companies in using NAD to challenge prescription drug advertising[8]. At NAD's 2022 annual conference, the company shared that its cases over the prior year included drugs and dietary supplements. It's increasingly important for companies to review advertising strategies both with consideration of FTC standards and the potential for an NAD challenge in mind.

How Healthcare Firms Achieve & Demonstrate Marketing Compliance

There is no margin for error in the healthcare sector when it comes to adhering to marketing compliance rules. With so many industry regulations to consider, managing marketing workflows in a spreadsheet while remaining productive and compliant is a tremendous challenge

Using a system of record like IntelligenceBank, healthcare companies can demonstrate marketing compliance through a combination of proactive approval measures, content automation and reporting.

These are some of the ways IntelligenceBank's hospital, pharmaceutical and health services clients use IntelligenceBank to help ensure marketing compliance.

Automating and Standardizing Disclaimers

IntelligenceBank's Disclaimer Engine reduces the risk associated with marketing errors by standardizing legally approved disclaimer language. This tool enables the generation of legally approved disclaimers, aligning with criteria established in collaboration with your legal team.

- Eliminate the need for individual legal review and approval of disclaimers for each creative asset; instead, gain efficiency by approving disclaimer rules at the commencement of a campaign.
- Enhance production speed by automatically incorporating disclaimers into every artwork piece within a campaign.
- Establish a comprehensive database of approved disclaimers and employ Creative Templates to swiftly integrate disclaimers into creative content.
- Address space constraints on digital banners with ease.
- Establish rules that automatically adapt the length of a disclaimer based on the channel in which it will be utilized.

> **The nature of the compliance component is that it is a requirement that sits on top of that creativity and all of that great work that people do for customers for building the brand. I think in everything that is designed in using a platform like IntelligenceBank, it's about ensuring that, supporting that ideation work, that design work, that creativity and the focus on the customer.**
>
> Euan Ferguson | Marketing Operations and Planning
>
> medibank

Tracking Critical Content Reviews and Updates

The Content & Collateral Tracker ensures critical information – pricing, patient information, support service and more – are updated regularly and do not pose a compliance threat.

The products make it easy to assign webpages, documents, promotional material and other assets to specific reviewers, set review cycles, and get alerted when a review is due. Marketers can then collaborate with colleagues to make changes and upload the latest approved version to be reviewed again. A dashboard empowers team members to monitor progress and activity.

Here's how it works:

- Each asset is named and tagged with a review cycle time period (eg 30/60/365 days)
- 30 days before each asset is up for review, an email alert is sent
- The asset is reviewed and shared with other collaborators for input
- Updates are made and the version is approved
- The asset is then updated in the IntelligenceBank DAM as a new version of the asset and a new review cycle is started
- A full record of the asset review and approval is kept for future reference, especially if audited

This is a particularly useful tool for US healthcare marketers where Hospital Price Transparency is mandated[9], yet as of January 2024, nearly 10% of hospitals remain non-compliant[10].

Streamlined Content Approval Workflows

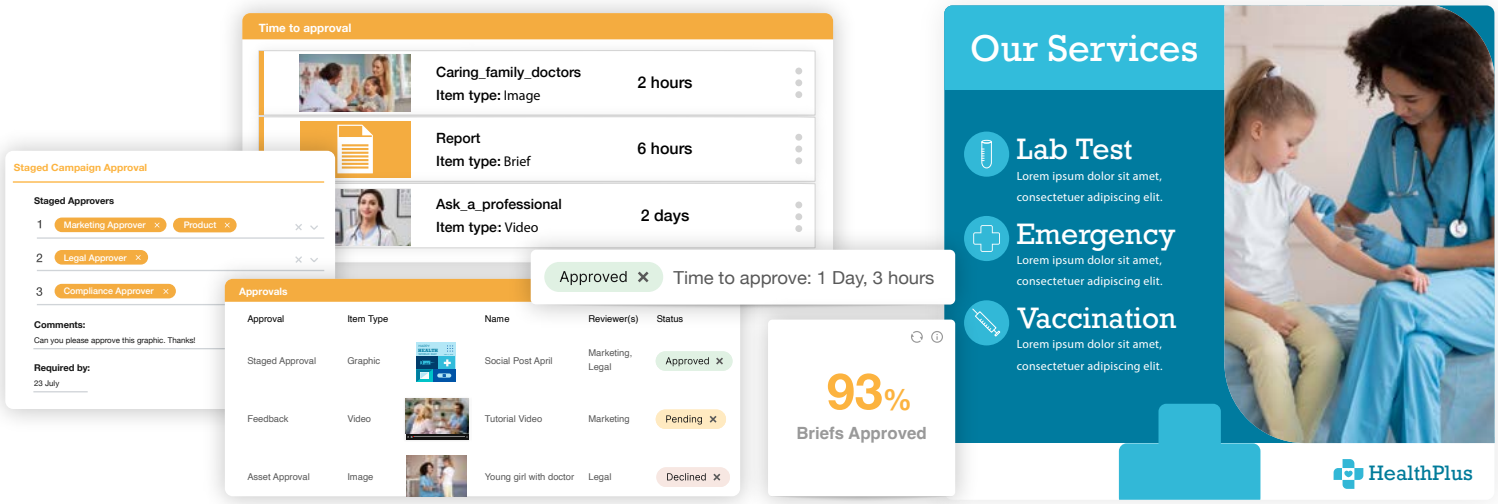
All too often, content that requires approval – especially from legal or compliance teams – ends up in email or other tools. Highly productive and compliant teams use a streamlined approval process such as the one in IntelligenceBank.

Customers using the workflow approvals tool are empowered to streamline their processes and gain enhanced visibility throughout the approval lifecycle. By transitioning creative approval requests away from email and onto a dedicated platform, users maintain a comprehensive record of all actions taken. The platform allows customers to configure approval workflows to align with their unique needs, supporting single, multi-stage, or conditional approvals.

Automation capabilities enable the implementation of workflows based on personalized conditions such as campaign type, stage, budget, or risk level. Users can customize approver roles and timelines, ensuring flexibility and control.

Access to approval history for any asset is simplified, eliminating the need to search through old emails. With a detailed record at their fingertips, customers can confidently review approver details, comments, and approval dates for any asset or brief. This approach not only expedites the approval process but also provides insights into potential bottlenecks.

Constant monitoring of individual and team performance, coupled with detailed reports, empowers users to identify and address issues efficiently while recognizing top performers.



IntelligenceBank has been essential to providing a central location for up-to-date assets and materials where we can share instantly across our system in a rapidly changing environment.

Andrew McLeroy | Creative Director

BAPTIST HEALTH

Maintaining Auditible Activity Visibility and History

Maintaining an audit trail is essential – and something that is nearly impossible to do in a spreadsheet or multiple systems you might use for asset storage, workflow and creative development.

IntelligenceBank maintains a complete audit trail of actions within the platform marketers use for workflow, markup, revision history, approvals, distribution and more, helping teams easily comply with banking and advertising regulatory requirements.

In addition, customers using IntelligenceBank's Smart Reports can also easily use dashboards to get granular insight into:

- How many assets or briefs require approval or review at any time
- Speed to approval by request type and resource
- Overdue approvals
- Creative briefs not approved or approved briefs with no related, approved assets.

Such insights make it possible to remove blockers, optimize slow processes and also praise colleagues who are helping their peers get content out the door fast – legal and brand approved.

Standardized Creative Templates

Due to compliance concerns, healthcare sector marketers work with more guardrails than marketers in most industries. This can lead to decreased productivity. That's why most IntelligenceBank customers use standardized creative templates.

Empowering users to produce brand-approved content at scale, the standardized content templates offer a streamlined process for creating multiple variations of assets. With the ability to automatically integrate disclaimers, approved imagery, product names, and locations into collateral through user-friendly drop-down lists, customers gain enhanced visibility and control over the content production process.

In addition, the product enables a broad spectrum of individuals to become content creators. Users can create templates, determine editable elements, and establish locked-down components, allowing anyone to generate their own brand-approved assets. This approach democratizes content creation, fostering a sense of empowerment among diverse users.

By facilitating small-scale design edits for a wider audience, the product provides more time for creative professionals to focus on impactful and meaningful work. This shift away from repetitive and time-consuming tasks allows the creative team to dedicate their efforts to endeavors that hold the utmost significance.

Using AI to Help Manage Talent or Content Usage Expiration Rights

An important aspect of healthcare marketing is keeping on top of talent usage in all content. This includes patients, healthcare workers and professional talent. Ensuring patient permissions are sought and updated is as important as paid talent rights. This also applies to healthcare workers or executives featured in marketing content that may have left the organization.

Using AI facial recognition technology embedded into the same platform you use for asset storage, marketing workflow and approvals (such as IntelligenceBank) can save untold hours identifying and changing out photographs across marketing collateral.

For example, imagine a team member needs to explore whether an individual or a license image has been used across various mediums such as web pages, videos on various social platforms and more. A manual search might take hours or days. However, using object recognition tags and face recognition tags (auto-tagged using AI upon upload) makes the process of locating those assets incredibly easy.

IntelligenceBank knows compliance. With auditable collaboration and automated processes around briefs, disclaimers and creative templates, our clients report a dramatic drop in compliance missteps.

Luminis Health

uses IntelligenceBank to boost creative compliance and efficiency:

44

Templates to automate local ad creation

600

Visitors per quarter to their online brand guidelines

9000

Managed digital assets including headshots, icons, logos, images and creative templates

23%

Time saved on brand admin and content compliance

Marketing Compliance Overview

Healthcare marketers are subject to stringent regulations imposed by government agencies and regulatory bodies. These regulations aim to uphold ethical practices, ensure patient safety, maintain the integrity of healthcare markets, and safeguard patient privacy.

This list is by no means exhaustive, but here are some of the basics that healthcare marketing leaders should keep in mind.

Non-compliance with these regulations can lead to severe penalties, fines, legal actions, and tarnish the reputation of healthcare institutions.

Patient Protection

- Healthcare products and services often involve intricate medical information and treatment options. Compliance in healthcare marketing is crucial to ensure that promotional materials are truthful, clear, and don't mislead patients. This is vital for protecting patients from making ill-informed decisions that could negatively impact their health outcomes.

Building Trust and Reputation

- Trust is paramount in the healthcare industry. Adherence to marketing regulations fosters trust with patients and the broader public. A positive reputation is invaluable for healthcare organizations, and compliance plays a vital role in upholding integrity.

Preventing Fraud and Misrepresentation

- Stringent compliance measures in healthcare marketing help thwart misinformation, fraudulent activities and misrepresentations. By maintaining accuracy and transparency in marketing communications, healthcare institutions can mitigate exploitation of vulnerable patients.

Market Confidence

- Compliance with marketing regulations contributes to the overall confidence and integrity of healthcare markets. Misleading or deceptive marketing can undermine market stability by eroding trust from patients, healthcare providers and investors.

Risk Management

- Non-compliance poses significant risks to healthcare organizations, including legal liabilities and financial repercussions. Implementing robust marketing compliance measures enables institutions to identify and mitigate these risks effectively.

Navigating Global and Local Regulations

- Healthcare marketers often operate in diverse regulatory environments, each with its unique requirements. Ensuring compliance with both global and local standards and regulations is essential for the seamless delivery of healthcare services across borders.

Adaptation to Regulatory Changes

- Healthcare regulations evolve continually. Staying abreast of regulatory updates and adjusting marketing strategies and materials is critical to ensure ongoing compliance.

Regulating Agency Resources and Guidelines for Healthcare Marketers

There are many regulations global healthcare services marketers may want to become familiar with, but the following may be particularly important depending on where you operate.

For the sake of accuracy, this report links to each agency's website.

United States:

- Food and Drug Administration (FDA): Responsible for regulating the marketing and promotion of drugs, medical devices, biologics, and other healthcare products.
- Federal Trade Commission (FTC): Enforces regulations related to advertising and marketing practices, including those pertaining to healthcare products and services.
- Centers for Medicare & Medicaid Services (CMS): Oversees regulations related to marketing Medicare and Medicaid programs.
- Health Insurance Portability and Accountability Act (HIPAA): Ensures the privacy and security of patients' health information, which also applies to marketing activities.

European Union:

- European Medicines Agency (EMA): Regulates the marketing authorization of medicines, ensuring compliance with standards for safety, efficacy, and quality.
- European Commission Directorate-General for Health and Food Safety (DG SANTE): Develops and implements EU policies and legislation related to public health and healthcare products.
- General Data Protection Regulation (GDPR): Imposes strict requirements on the processing of personal data, including patient data, which impacts healthcare marketing efforts.

Canada:

- Health Canada: Similar to the FDA in the U.S., Health Canada regulates the marketing and promotion of drugs, medical devices, and other health products to ensure safety, efficacy, and quality.
- Advertising Standards Canada (ASC): Oversees advertising standards and self-regulation for non-prescription healthcare products and services.

Regulating Agency Resources and Guidelines for Healthcare Marketers

United Kingdom:

- Medicines and Healthcare products Regulatory Agency (MHRA): Regulates medicines, medical devices, and blood components for transfusion in the UK, including marketing authorization and safety monitoring.
- Advertising Standards Authority (ASA): Regulates advertising across various sectors, including healthcare, ensuring that ads are legal, decent, honest, and truthful.

Australia:

- Therapeutic Goods Administration (TGA): Regulates therapeutic goods, including medicines, medical devices, and blood products, ensuring their safety, efficacy, and quality.
- Australian Competition and Consumer Commission (ACCC): Enforces consumer protection and competition laws, including those related to advertising and marketing practices in healthcare.

***Discliamer:** this list is not exhaustive and is intended as a helpful guide only.*

References

1. Financial Times, February 7, 2024.
2. FTC.gov, Accessed February 20, 2024.
3. FDA News, February 16, 2024.
4. thebjm.com, February 15, 2024.
5. The Pharmaceutical Journal, March 17, 2023.
6. Mumbrella, December 7, 2023.
7. FTC.gov, October 11, 2023.
8. FDLI.org, Accessed February 26, 2024.
9. CMS.gov, November 2, 2023.
10. American Hospital Association, January 5, 2024.

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