# ONC Health IT (b)(11) DSI Requirements

## HTI-1 Market Survey Report

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# Executive Summary

This report presents the findings from a recent survey of Health IT developers focused on the challenges and timelines associated with achieving compliance with the new (b)(11) Decision Support Interventions (DSI) requirements under the ONC Health IT Certification Program. With the compliance deadline rapidly approaching, the survey reveals a broad spectrum of readiness levels and challenges among developers.

Key findings include that while **57% of respondents view the (b)(11) requirements as very or extremely challenging, over half (51%) anticipate their DSI compliance projects to take more than five (5) months. However, confidence in having sufficient internal resources to meet the compliance requirements is split, with 50% of respondents expressing low confidence.**

These insights underscore the need for accurate interpretation of compliance rules and for effective project planning to ensure successful compliance within the required timelines.

Market surveys like this one are invaluable tools for stakeholders, enabling them to gauge their readiness and challenges against those of their industry peers. The insights gained from such surveys provide a mechanism for stakeholders to double-check their assumptions, refine resource and project planning, and identify areas where additional support may be necessary.

Additionally, this data can serve as a critical resource in securing approval for changes to project plans or justifying the allocation of additional resources—whether internal or external. By offering a benchmark of industry-wide challenges and timelines, these surveys help organizations ensure that they are not only on track but also strategically positioned to meet regulatory requirements with confidence.

1. **Significant Challenges Ahead:**

   The majority of Health IT developers surveyed (57%) anticipate that meeting the (b)(11) DSI requirements will be very or extremely challenging. The complexity of understanding new categories like Predictive DSIs and managing compliance with evolving USCDI version requirements are seen as particularly difficult tasks.

2. **Significant Challenges Ahead:**

   Despite the recognized challenges, 79% of respondents believe their projects will take less than a year, with over half (51%) believing it will take more than five (5) months. However, there is a notable divide in confidence levels, as only 17% of respondents are very confident in their ability to meet the year-end deadline.

3. **Key Areas of Concern:**

   - Developing Risk Management Programs: Developing the required Intervention Risk Management (IRM) programs is another critical area, with 69% finding this very or extremely challenging.
   - Understanding Predictive DSIs: Half of the respondents rated understanding the impact of Predictive DSIs on their products as very or extremely challenging.
   - Internal Resource Constraints: The survey highlights that 50% of respondents are not confident in their internal resources' ability to achieve compliance, indicating a need for additional support.

4. **Potential Need for External Support:**

   Given the combination of tight timelines and significant challenges, many developers may benefit from engaging external advisory services. These services can provide the expertise necessary to interpret the new requirements correctly and help avoid costly rework or missed deadlines.

# DSI Applicability and Plans

Participants were asked if they have an ongoing project aimed at achieving (b)(11) DSI compliance within the current year. Additionally, they were asked about their current or future plans to provide predictive decision support capabilities within the next year.

**Over 50% of health IT developers could 'supply' predictive DSIs to their customer base, triggering Intervention Risk Management responsibilities.**

An almost equal number of health IT vendors responded "yes" (42%) and "no" (44%) when asked if they plan to supply predictive decision support capabilities, with 14% still undecided. With 42% already committed and 14% potentially entering the market, the data indicates that many vendors are likely to offer AI-driven capabilities soon.

However, this number may be underestimated. **The survey found that 88% of respondents find understanding the new "predictive" category somewhat to extremely challenging.** The highest-rated challenge was building an Intervention Risk Management (IRM) program—a critical requirement for those who supply or plan to supply predictive DSIs.

The complexity of source attribute requirements further complicates development in this area. Many developers may lack the necessary functionality to meet DSI and source attribute requirements. As a result, external support might be needed to supplement internal resources, ensure accurate rule interpretation, and create efficient project plans, increasing the chances of meeting deadlines.
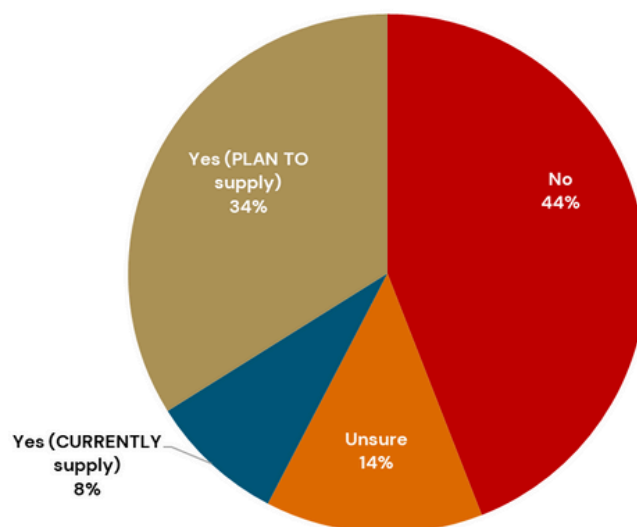
Do you currently have a project underway to achieve (b)(11) DSI compliance this year?
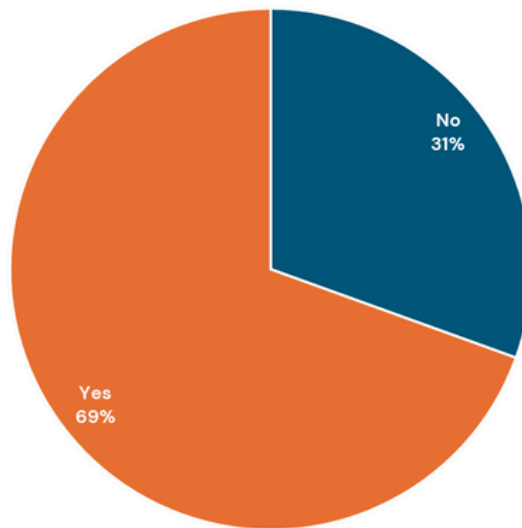


Do you currently supply, or plan to supply, predictive decision support capabilities within the next year?

Participants were asked to rank ten challenges they may experience as they work towards achieving (b)(11) DSI certification compliance requirements by the end of 2024.

**Analysis shows low confidence in DSI compliance readiness.**

Many respondents expressed low confidence in meeting DSI compliance deadlines, especially those with project timelines of six months or more. This concern is heightened among the 30% who have not yet started their (b)(11) compliance projects. Overall, only 17% of respondents felt "very confident" about meeting the deadlines.

This lack of confidence could stem from several factors including: limited understanding of the new "Predictive DSI" category, confusion between "enabling" and "supplying" DSIs, and delayed planning for the new requirements. To improve confidence, developers need a clear development and testing plan, supported by subject matter experts, to ensure they are ready to meet the compliance standards.
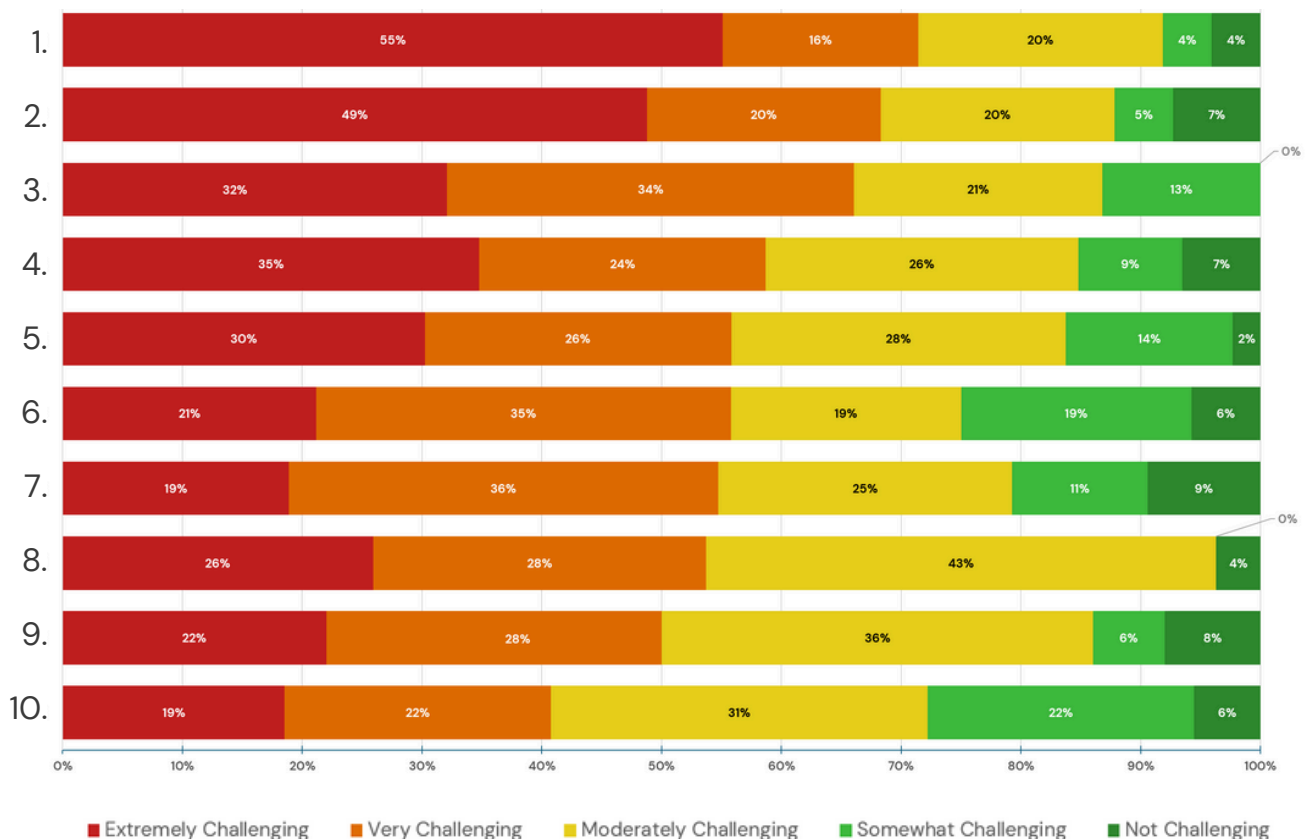
Risk management program development is also the 2nd biggest challenge area identified in the survey, although it only applies to developers who "supply" predictive DSIs. Since this area involves compliance program development rather than software development, and has requirements unique to the A.I. space, many developers may need to seek outside support for this work effort.

The source attribute disclosure requirements add further complexity, as they must be accessible inside the product U.I., putting the IRM program and related source attribute in the critical path product release of (b)(11) upgrades.

# Challenges

1. Designing feedback mechanisms for Evidence-Based DSIs
2. Understanding the new Predictive DSI category's impact on my product
3. Developing a plan for product feature changes to satisfy (b)(11)
4. Managing USCDI version requirements and compliance deadlines
5. Meeting Source Attribute requirements for DSIs supplied to customers
6. Planning for ongoing Conditions of Certification for Predictive DSIs
7. Evaluating 3rd-party software options to address DSI requirements
8. Meeting SED testing requirements under (g)(3) for (b)(11) certification
9. Building a risk management program for Predictive DSIs
10. Supporting Predictive DSIs without supplying them

| # | Extremely Challenging | Very Challenging | Moderately Challenging | Somewhat Challenging | Not Challenging |
|---|---|---|---|---|---|
| 1. | 55% | 16% | 20% | 4% | 4% |
| 2. | 49% | 20% | 20% | 5% | 7% |
| 3. | 32% | 34% | 21% | 13% | 0% |
| 4. | 35% | 24% | 26% | 9% | 7% |
| 5. | 30% | 26% | 28% | 14% | 2% |
| 6. | 21% | 35% | 19% | 19% | 6% |
| 7. | 19% | 36% | 25% | 11% | 9% |
| 8. | 26% | 28% | 43% | 4% | 0% |
| 9. | 22% | 28% | 36% | 6% | 8% |
| 10. | 19% | 22% | 31% | 22% | 6% |

Legend: ■ Extremely Challenging ■ Very Challenging ■ Moderately Challenging ■ Somewhat Challenging ■ Not Challenging
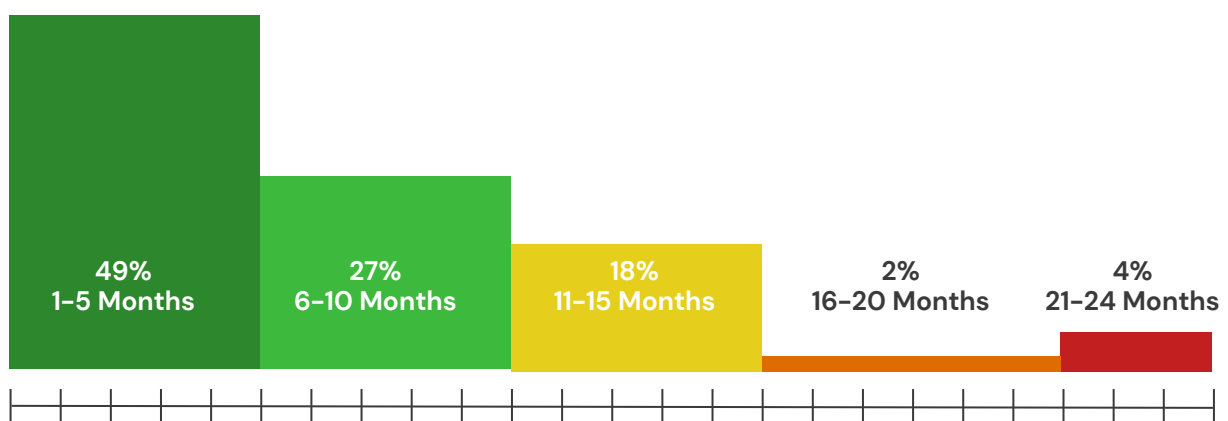
# Anticipated Project Length

**DRUMMOND**

Participants were asked to estimate (b)(11) DSI certification compliance project length in months.

**Nearly 70% of respondents have started their (b)(11) compliance projects, but over 50% estimate their projects will take six months or more to complete.**

With just 3.5 months remaining for submission of (b)(11) attestations to ACBs for year-end compliance, this extended timeline poses a significant challenge for health IT developers not yet well underway. Engaging consulting expertise to support planning and execution may be necessary.

Health IT developers might consider seeking external resources to ensure accurate interpretation of the rules as they apply to their unique environments, reducing the risk of rework and ensuring their development plans are both efficient and effective.

Additionally, developers could consider phasing their release schedules for "to-be-supplied" DSIs and focus on meeting DSI platform support requirements in 2024 to stay on track.

| 49% | 27% | 18% | 2% | 4% |
|---|---|---|---|---|
| 1–5 Months | 6–10 Months | 11–15 Months | 16–20 Months | 21–24 Months |

# Internal Resources

The survey also explored participants' confidence in their internal resources to achieve (b)(11) DSI compliance within the required timelines. The results highlight a significant divide, with 50% of respondents expressing doubts about having adequate internal resources.
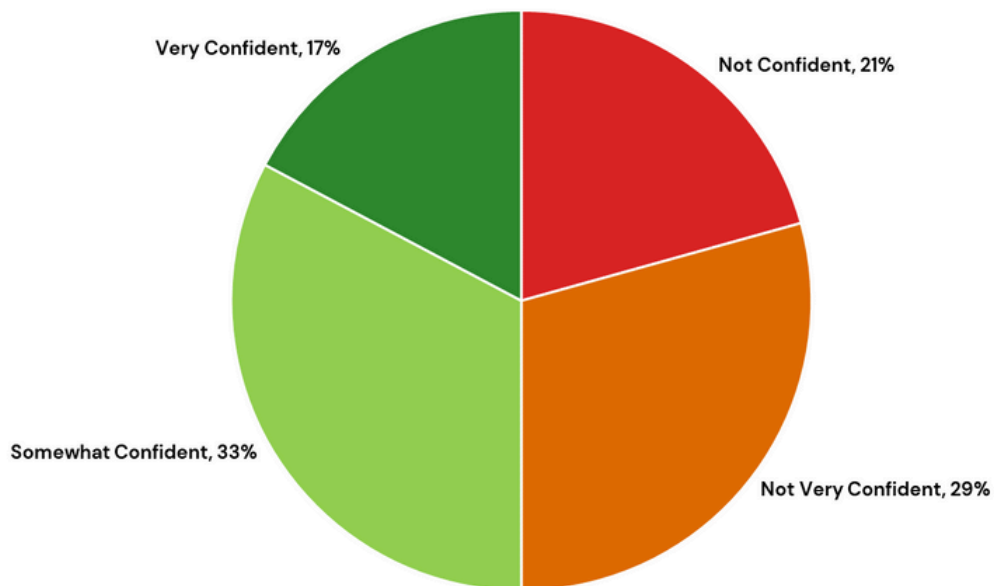
# Conclusion

The survey results reflect the complex and demanding nature of the new (b)(11) DSI requirements under the ONC Health IT Certification Program. While most developers recognize the challenges, the short timeline for compliance, coupled with varying confidence levels, suggests that many organizations may struggle to meet the deadline without external support. The findings indicate a strong need for clear, actionable plans, and potentially the inclusion of third-party advisory services to ensure that all requirements are met efficiently and effectively.

As the compliance deadline approaches, Health IT developers should prioritize understanding the Predictive DSI requirements, building robust risk management programs, and assessing their internal capabilities to determine whether additional external resources are necessary to meet their compliance goals. Ensuring that projects are well-planned and adequately resourced will be critical to achieving compliance and maintaining certification under the ONC Health IT framework.

## Please Note:

As the predominant leader in ONC Health IT testing and certification, Drummond gathered insights from over 10% of it's health IT developer customers. The survey was open to participants for 30 days starting early July 2024. While this group represents a select segment of the industry, their responses offer valuable perspectives on the challenges and readiness levels associated with meeting the new (b)(11) DSI requirements. These insights provide a meaningful snapshot of industry trends and serve as a practical benchmark for developers navigating this complex compliance landscape.

Services offered by Drummond Advisory Services are separate and distinct from the Drummond Group Test Lab and Certification Body. The purpose of Drummond Advisory Services is to provide expert support and guidance for the planning, analysis, and execution of certification activities; it does not negate the steps or required actions of the certification process. Use of Drummond Advisory Services does not guarantee successful ONC Health IT testing or certification.

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Get the resources you need to meet the challenges associated with (b)(11) DSI criterion. Our experts will provide clear, actionable insights on criterion interpretation and implementation. Understand how these mandates apply to your specific environment, streamline your development process, and avoid costly mistakes.

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