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Business Preparedness & Continuity Consulting Services

WHITE PAPER

EMERGENCY PREPAREDNESS REQUIREMENTS FOR MEDICARE & MEDICAID PROVIDERS

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Accinctus LLC provides business continuity services to include assessments, planning, training, and program compliance reviews to assist any business or organization prepare for disasters and disruptions. Accinctus LLC is a Veteran Owned Small Business.

I. Introduction

The focus of the medical profession is on caring for others. It can be a difficult challenge under normal (ideal) conditions, but what happens when "normal" is disrupted by a natural or man-made disaster? Are most medical providers such as hospitals, long-term care facilities, or regional clinics prepared for disasters and disruptions that dramatically increase both the need for their services and the difficulty of the environment they must provide those services in?

Unfortunately, lessons learned from small, local events up to large, regional disasters show that health care providers and suppliers across the country are inconsistent in their emergency preparedness with many organizations unprepared for even small emergencies. This problem is certainly not limited to the health care industry; studies show most businesses in the U.S. do not have business continuity or emergency operations plans in place either.

One of the main reasons for the general deficiency of organizational preparedness in the U.S. is the lack of firm regulatory requirements. There are voluntary standards such as ISO 22301 and NFPA 1600 which provide guidance on business continuity program implementation while a few other laws may address specific requirements for data protection (e.g. HIPAA) or risk management (e.g. Sarbanes-Oxley), but no laws require comprehensive emergency operations or business continuity programs.

To resolve this issue in the medical services community, the Department of Health and Human Services (HHS) has proposed a change to federal regulations that would standardize the vast variety of preparedness requirements across the 17 types of providers and suppliers participating in Medicare and Medicaid programs. This is expected approval in mid-2015. (Federal Register – Document Text)

This white paper addresses the new requirements and includes options for affected organizations to effectively develop an emergency preparedness program in compliance with the rule.

II. Discussion

The Department of Health and Human Services (HHS) has conducted a comprehensive examination of the current state of preparedness for health care services, the regulatory environment for these organizations, and lessons from disasters such as Hurricane Katrina, the attacks on September 11th, Hurricane Sandy, forest fires in the West, the cycles of pandemic influenza, tornados and floods in the Midwest, and many other events. One of the critical gaps HHS identified is that the current regulatory patchwork of laws and guidance is inadequate to prepare health care providers and suppliers for disasters.

To drive positive change, HHS is proposing an update to the requirements stated in 42 CFR, Centers for Medicare and Medicaid Services. This new regulation "…would

establish national emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It would also ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disaster and emergency situations."[i]

There are several questions that quickly surface in regards to the proposed changes.

1. Why are these changes required by law?
2. What organizations are affected by the new requirements?
3. How long will an organization have to become compliant?
4. What are the required actions of the new rule?

Question 1: Why are these changes required by law?

In researching the myriad of regulations and guidance currently available it is easy to agree from a professional business continuity perspective with the HHS assessment regarding two key conclusions.

The HHS report states: "The current regulatory patchwork of federal, state, and local laws and guidelines, combined with the various accrediting organization emergency preparedness standards, falls far short of what is needed to require that health care providers and suppliers be adequately prepared for a disaster." [ii]

The first conclusion keys on the "patchwork" of laws, guidelines, and accrediting standards that must be complied with. Some (but not all) of the sources include:

- Department of Health and Human Services (HHS)
- Food and Drug Administration (FDA)
- Centers for Disease Control (CDC)
- Health Resources and Services Administration (HRSA)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- The Joint Commission (TJC) Standards for Emergency Preparedness
- American Osteopathic Association (AOA) Standards for Disaster Preparedness
- National Fire Protection Association (NFPA) standards 101 (Life Safety) and 1600 (Standard on Disaster/Emergency Management and Business Continuity Programs)
- Emergency preparedness requirements in the different Conditions of Participation (COP)

Simply, there are too many regulations organizations must sift through to determine what they need to do to remain in compliance. The lack of consistent requirements results in preparedness programs (when implemented at all) that are inconsistent and incapable of working together during disasters. HHS determined that creating consistent standards at a higher level would be the most effective solution.

The second conclusion is that the current laws and guidelines are not comprehensive enough to prepare organizations for actual disasters. This, I believe, is the more significant of the shortfalls in current guidance. Traditionally health care providers focus on critical medical response during a disaster (similar to how police and fire departments approach disasters: response, response, response). From a business continuity perspective I have observed that these organizations rarely focus on the impact of the disaster on their own agency, internal staff, and service capabilities outside of emergency response. This narrow focus leaves the organizations, particularly those agencies with less regulatory guidance, vulnerable when it comes to mitigation, response, and recovery operations and at greater long term risk.

Because disasters can disrupt the health care environment at times of greater need for healthcare services, it is essential that health care providers and suppliers establish emergency preparedness programs in a consistent and effective manner. HHS concluded that the best way to positively improve the system is to improve standardization and increase effective preparedness requirements in a single rule for all applicable providers and suppliers.

Question 2: What organizations are affected by the new requirements?

The consolidated preparedness requirements will apply to the 17 provider and supplier types that participate in Medicare and Medicaid programs. [iii]
These organizations include:

1. Religious Nonmedical Health Care Institutions (RNHCIs)
2. Ambulatory Surgical Centers (ASCs)
3. Hospices
4. Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs (PRTFs)
5. Programs for All-Inclusive Care for the Elderly (PACE)
6. Hospitals
7. Transplant Centers
8. Long Term Care (LTC) Facilities – Skilled Nursing Facilities (SNFs)
9. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
10. Home Health Agencies (HHAs)
11. Comprehensive Outpatient Rehabilitation Facilities (CORFs)
12. Critical Access Hospitals (CAHs)
13. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
14. Community Mental Health Centers (CMHCs)
15. Organ Procurement Organizations (OPOs)
16. Rural Health Clinics (RHCs)
17. End-Stage Renal Disease (ESRD) Facilities

The proposed requirements will include limited variances for specific types of providers and suppliers. For example, shelter in place and emergency supply requirements may be different for a hospital as compared to a provider with no inpatient services.

Question 3: How long will an organization have to become compliant with the new requirements?

The requirements will be consistent and enforceable for all affected Medicare & Medicaid providers and suppliers. HHS considered different timeline alternatives and is proposing "to implement all of the requirements 1 year after the final rule is published." [iv]

From my professional perspective, any agency that waits till the end of that year to begin developing their program risks failure and I recommend organizations begin preparing as soon as possible.

Question 4: What are the required actions of the new rule?

The focus of the new rule is to ensure health care services are available during emergencies and disasters by "safeguarding human resources, ensuring business continuity, and protecting physical resources." [v]

To meet this goal, HHS has identified 4 core elements for an effective emergency preparedness program. The 4 core elements are:

1. Risk Assessment and Planning: Each provider or supplier is required to conduct a comprehensive all-hazards risk assessment.
2. Policies and Procedures: Organizations are required to develop and implement emergency policies and procedures (i.e. plans) based on the risk assessment.
3. Communication Plan: Organizations are required to develop an emergency preparedness communication plan in compliance with federal, state, and local laws.
4. Training and Testing. An organization must establish an emergency preparedness training and testing program that provides initial training in emergency preparedness policies and procedures and requires annual exercises as a minimum to demonstrate the organization's ability to execute those plans and procedures.

III. Options

The establishment of an emergency preparedness program for a health care provider or supplier based on the HHS 4 core elements aligns with the standard business continuity process. This process is defined in NFPA 1600 and ISO 22301 standards, which are also integrated into the Department of Homeland Security (DHS) Private Sector Preparedness (PS-Prep) program.

There are three potential solution paths an organization may consider to develop their emergency preparedness program and ensure compliance with the requirements. These options are very similar to the choices any business evaluates when establishing business continuity or preparedness programs: utilize in-house resources; hire a trained professional; or utilize a professional service provider. Depending on the needs and

scope of the program, an organization may utilize any of these options in combination to find a valuable solution.

Solution 1: Utilize In-House Resources

An organization may assign a current manager the responsibility to develop their emergency preparedness program. This emergency preparedness manager should have a solid working knowledge of the role and responsibilities of the organization as well as business continuity or emergency preparedness program implementation. Larger medical providers such as hospitals may have a preparedness or business continuity manager already assigned. Smaller organizations or those without traditional disaster response services, i.e. long term care facilities, are not likely have a full time professional on staff.

There are several risks with this option starting with the length of time it would take for a newly assigned coordinator to develop comprehensive knowledge of the preparedness program implementation process. The coordinator would need in-depth training. Assigning this program to an internal staff member will also take that person from current duties or result in the development of the preparedness program to a lower priority, risking non-compliance and an ineffective preparedness program. This endangers customers and personnel and will increase costs and liability.

If pursuing this option, the organization should consider additional assistance from a business continuity professional to ensure implementation to meet all program requirements.

Solution 2: Hire a Trained Business Continuity Professional

Hospitals and larger organizations may need a full time emergency program manager and should consider hiring a trained professional on a full time position (if not already on staff). As every organization knows, full time employees bring a great value to an organization but also a large cost depending on the skill set required.

Risks with this option are both the cost of a full time employee and the limited pool of available trained and certified business continuity professionals that may be available to hire.

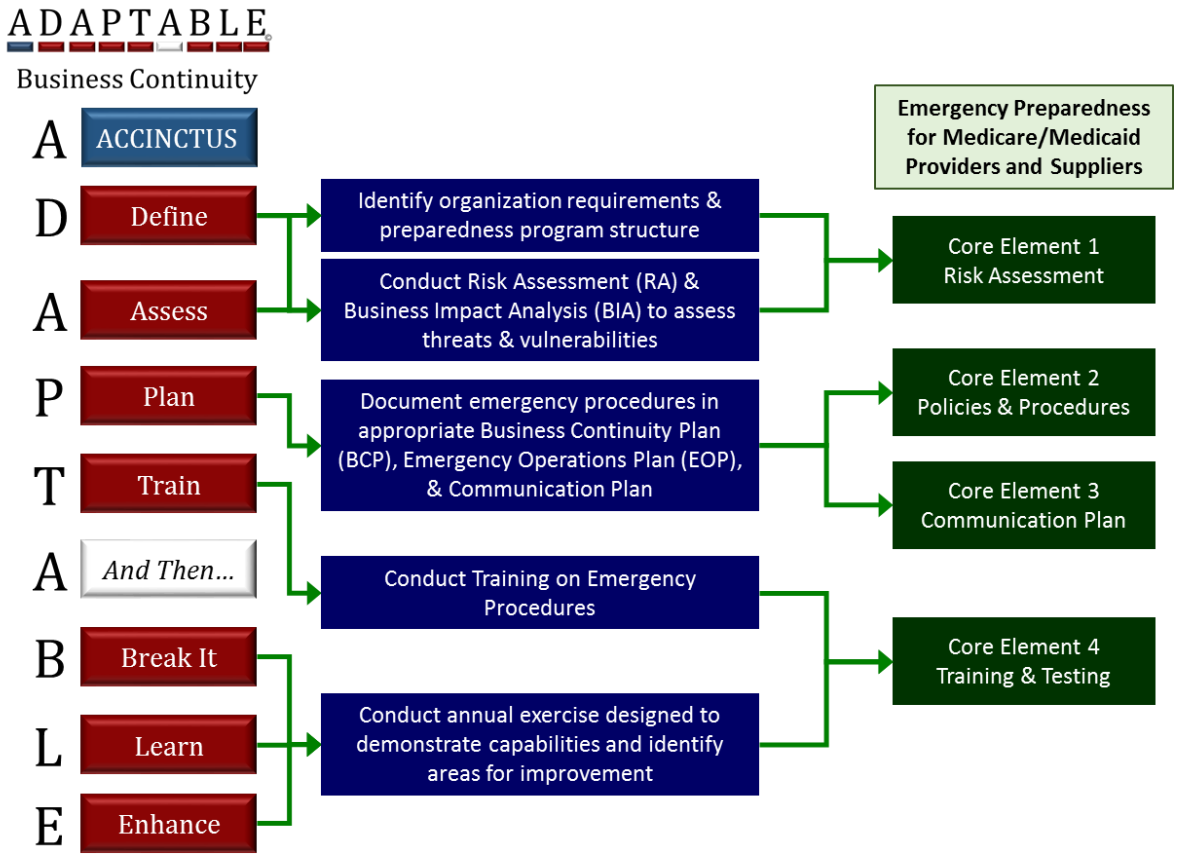
Solution 3: Utilize a Professional Business Continuity Service Provider

Outsourcing the development and implementation of an organization's emergency preparedness program may be a valuable option for small and medium organizations that do not have the budgetary resources to hire a full time professional. Every business has implemented the concept of "do more with less" in the last few decades and it is unlikely any staff members are just looking for more work to do, especially someone with the experience and skills to manage an emergency preparedness program. If an organization wishes to utilize internal resources, supplementing their program with professional assistance may be a balanced solution.

The risks with this option are that some outsourcing options may be expensive or that finding a service provider to specifically fit the organizations scope of requirements may be difficult. For example, a Long Term Care (LTC) / Skilled Nursing Facility (SNF) may need assistance in conducting the risk assessment and developing policies and a program structure, while they are comfortable developing their own plans and then later look for help developing training programs. Not all service providers may be flexible to address just those requirements of their program.

IV. Accinctus Solution

The Accinctus approach utilizes our ADAPTABLE© business continuity model, which is based on ISO 22301, NFPA 1600, and business continuity professional practices. ADAPTABLE© is a flexible utilization of the business continuity process that begins with defining the requirements, conducting a Risk Assessment (RA) and Business Impact Analysis (BIA), developing appropriate plans and processes which are then incorporated into tailored training programs. Exercises and tests are conducted to "break" those processes and identify ways to improve. This process matches with the 4 core elements required by HHS as shown in the Accinctus ADAPTABLE© Service-to-Solution model below.



Accinctus has experience implementing and managing preparedness programs in military, federal government, contract, and the private sector from the enterprise size down to small business and understands that every client is unique, so a cookie cutter

approach treating everyone the same just doesn't work. To ensure you receive the best value for your investment, the Accinctus approach allows you the flexibility to apply our capabilities to develop your emergency preparedness program in compliance with HHS requirements in a tailored manner. Options may include long term, project focused, or a flexible hours-per-month arrangement called *BC Pro-Flex* (a Business Continuity Professional with set hours per month to work on any facet of your preparedness program and priorities). Accinctus also provides training classes and workshops specifically designed to help any organization develop their own emergency preparedness program.

V. Summary

The Department of Health and Human Services has identified a significant need for standardized guidance to all Medicare and Medicaid providers and suppliers for emergency preparedness programs. They have proposed a rule change to require all 17 types of Medicare and Medicaid providers or suppliers to implement an effective emergency preparedness program that will include 4 key elements to protect lives and ensure continuity of critical medical services.

These key elements that all organizations must comply with are: conduct a comprehensive risk assessment; implement policies and procedures (plans) based on the identified risks; develop an emergency communication plan; and conduct initial and annual training and exercises for all staff to ensure the organization can effectively execute those defined emergency procedures.

Hospitals and larger organizations may have professional staff to develop or modify their current programs to comply with the HHS requirements. However, small and medium organizations may not have staff with the appropriate skills and available resources to complete these tasks and are at risk of non-compliance.

Accinctus provides business continuity services to develop an emergency preparedness program to meet the HHS 4 core elements. For questions or more information, contact Accinctus via email at questions@accinctus.com.

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[i] Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, 494; Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Proposed Rule

[ii] Ibid, Section I.A.1.

[iii] Ibid, Section I.C.

[iv] Ibid, Section IV, W.

[v] Ibid, Section I.A.2.