

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

CLUSTER DANIELS, ET AL., )

Plaintiffs, )

and )

C.J. by his next friend, C.S.; )  
H.G.; H.B. by her next friend, )  
W.M.; M.T. by her next friend, )  
M.T.; and M.C., )  
as representative class members, )

Plaintiffs, )

v. )

FREDIA WADLEY, Commissioner, )  
Tennessee Department of Health; )  
LINDA RUDOLPH, Commissioner, )  
Tennessee Department of Human Services, )  
ROBERT CORKER, Commissioner, )  
Tennessee Department of )  
Finance and Administration; )  
DONNA SHALALA, Secretary, )  
United States Department of )  
Health and Human Services; )  
BRUCE VLADECK, Administrator, )  
Health Care Financing Administration; )  
SHIRLEY CHATER, Commissioner, )  
Social Security Administration, )

Defendants. )

Civil Action )  
No. 79-3107-NA-CV )  
JUDGE NIXON )

RECEIVED  
IN CLERK'S OFFICE  
AUG 12 1996  
U.S. DISTRICT COURT  
MID. DIST. TENN.



**AGREED ORDER MODIFYING**  
**SECOND CONSENT DECREE [DOC. NO. 278]**

As a result of the implementation of the TennCare program, current provisions of the Second Consent Decree for assuring due process protection are inadequate. Therefore, the parties propose the following modifications:

This document was entered on the docket in compliance with Rule 53 and/or Rule 79(a) FRCP, on 8/27/96 By: [Signature] 387

## Premises

1. These modifications are submitted in compliance with the Court's memorandum and order entered on May 15, 1996 (Doc. Nos. 376 and 377).
2. Following extensive negotiations, the parties have attempted in good faith to devise revisions to the TennCare hearing procedures to assure that the Medicaid Due Process sub-class has "strong due process protections to protect themselves from inappropriate denials of health care" noted by this Court. Doc. No. 376: Memorandum, p. 5.
3. Without admitting that non-Medicaid eligible TennCare enrollees must be afforded due process protections and with the parties' recognition that defendants are free to alter these procedures, so long as those procedures satisfy due process, defendants are providing non-Medicaid eligible TennCare enrollees the same procedures that are afforded Medicaid-eligible TennCare enrollees in this consent.<sup>1</sup>
4. The TennCare Partners Program, which established a care management role for Behavioral Health Organizations (BHOs) similar to the TennCare MCOs' role in managing medical care, was implemented on July 1, 1996. The parties recognize that this Court's memorandum opinion does not address Behavioral Health Organizations (BHOs), which manage medical assistance services for mental illness and chemical dependency, and the TennCare Partners Program, which integrates behavioral health services into TennCare's managed care system.

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<sup>1</sup> The Court's Memorandum Opinion recognized that only "Medicaid-eligible enrollees" are covered by this lawsuit. Doc. No. 376, p. 2., N. 1.

## **Definitions**

5. "Defendants" as defined in the Second Decree included the state agency designated to administer the Tennessee Medicaid Program and its successors. The parties acknowledge that the Tennessee Department of Finance and Administration and the TennCare Bureau, with assistance of the Tennessee Department of Human Services and the Tennessee Department of Mental Health and Mental Retardation (TDMHMR), administers and supervises the Tennessee Medicaid (TennCare) Program.

6. The phrase "Tennessee Medicaid Program" shall refer to the joint federal/state medical assistance program administered pursuant to Title XIX of The Social Security Act, 42 U.S.C. §§ 1396 et seq. (hereinafter "Medicaid Act"), including Tennessee's Medicaid Demonstration Project Number 11-C-99638/4-03 called "TennCare."

7. The term "medical assistance services" means care, services, drugs, equipment and supplies prescribed as medically necessary to prevent, diagnose, correct, or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, or interfere with or threaten some significant impairment and which are furnished in accordance with the Title XIX of the Social Security Act and the T.C.A. 71-5-101, et seq. Such care, services, drugs and supplies shall include services of qualified practitioners licensed under the laws of the State of Tennessee. See T.C.A. 71-5-214.

8. The term "enrollee" shall mean any person enrolled under TennCare to receive medical assistance at any time on and after January 1, 1994 and anyone who may be enrolled in the future. An authorized or legal representative of an enrollee has the right to make any appeal or request any hearing, receive copies of all notifications after an inquiry, and otherwise act on behalf of an enrollee under the provisions of this Order where such right would be available to

the enrollee. Provided, however, the defendants must be notified of such authorized representative status. This definition of "enrollee" is not intended to amend the definition of any class or sub-class previously certified by the court, which is limited to "Medicaid-eligible enrollees."

9. The term managed care organization (MCO) means any person, institution, agency, or business concern that contracts with the State of Tennessee to provide medical assistance to TennCare enrollees. A Behavioral Health Organization ("BHO") is an entity that contracts with the State of Tennessee to provide medical assistance to TennCare enrollees as part of the "TennCare Partners Program."

10. "Urgent care" means medical assistance services which the enrollee or the enrollee's parent, legal guardian or representative and the primary care provider or treating specialist have attested are required promptly to prevent substantial deterioration of the individual's health status and the failure to provide such services promptly is likely to cause substantial harm.

11. All definitions of the Second Consent Decree that are not inconsistent with the above definitions shall remain in full force and effect.

### **Intent**

12. Medicaid-eligible TennCare enrollees have a right to due process protections whenever State defendants, BHOs, or MCOs take action to suspend, terminate or reduce services and, in particular, to deny requests for prior approval of medical assistance. See e.g., 42 U.S.C. § 1396a(a)(3) and 42 C.F.R. pt. 431, subpt. E. These modifications to the Second Consent Decree are intended to assure the "strong due process protections to protect themselves from

inappropriate denials of health care" specified by this Court. Doc. No. 376: Memorandum, p. 5. These protections are set forth in a new Section II replacing the prior section in the Second Consent Decree.

13. The provisions which follow are intended to replace the provisions under Sections II, IV, and VII of the Second Consent Decree [Doc. 278]. Section V expired by its own terms. All other provisions of the Second Consent Decree [Doc. 278], to the extent that they are not inconsistent or contrary to the provisions herein, remain in full force and effect. By retaining those provisions, the parties do not imply creation of new duties.

#### **Exclusions and Reservations**

14. In addition to the reservations and exclusions under ¶ 25 of the Second Consent Decree [Doc. 278], which remain in full force and effect, the parties recognize that the District Court's Order excludes any issues related to non-Medicaid eligible TennCare enrollees.

15. Affidavits of plaintiff class members allege instances where medical assistance services were denied, terminated, suspended, reduced or delayed. Where possible, plaintiffs' counsel have diligently sought to obtain necessary services. The TennCare Bureau and its employees have attempted to resolve disputes over medical assistance services to protect enrollees from inappropriate denial of health care and from harm. As to defendant State officials, this modification to the Second Consent shall not affect the right of any individual class member to seek any and all relief that is otherwise available through administrative review proceedings authorized by state and federal law, or through proceedings against the State before the Tennessee Claims Commission based upon alleged actions or omissions of the State defendants. It is intended to adjudicate with respect to the class and the individual members of the class those

claims for relief which were made on their behalf in these proceedings, and to thus bar further proceedings by class members seeking the same relief under 42 USC § 1983. The parties acknowledge the State may assert any and all defenses available in any such administrative, Claims Commission or other litigation.

16. The parties recognize that the Health Care Financing Administration ("HCFA") has the authority to grant future waivers of specific requirements of the Medicaid Act and its exercise of such authority governs the TennCare Demonstration Project.

17. The plaintiffs hereby withdraw any currently pending Motions related to this case, including any relating to alleged Contempt by the State defendants.

### **ORDER**

The Court expressly approves these modifications to the Second Consent Decree and further finds that these modifications afford plaintiffs sufficient due process protections together with enhanced monitoring of MCOs and BHOs by defendants to protect enrollees from inappropriate denials, terminations, suspensions, reductions or delays of medical assistance services under Tennessee's managed care Medicaid demonstration project called TennCare. Approval of these modifications is in the best interest of the plaintiffs and constitutes a counter-balance to the pecuniary incentives this Court found MCOs have for denying, terminating, suspending, reducing or delaying health care. See Doc. 376, p. 5.

**THEREFORE, upon the consent of the parties hereto, it is hereby ORDERED, ADJUDGED AND DECREED that the Second Consent Decree [Doc. No. 278] be modified as follows:**

18. Section II is deleted and a new Section II shall be inserted to read as follows:

## **II. NOTICE AND APPEAL PROCESSES**

1. A plain language written notice shall be given to an enrollee by her/his Managed Care Organization (MCO), Behavior Health Organization (BHO) or the TennCare Bureau of any action, as defined at 42 CFR 431.201, to deny, terminate, suspend or reduce medical assistance.

2. A prior written notice shall be given to an enrollee by her/his Managed Care Organization (MCO), Behavior Health Organization (BHO) or the TennCare Bureau of any action that reduces, suspends or terminates medical assistance and the notice must be received by the enrollee prior to the date of proposed reduction, suspension or termination unless one of the exceptions exists under 42 CFR 431.211-214.

3. Written notices, in a format approved by the TennCare Bureau, must include:

- a. Description of the medical assistance;
- b. Identification of the provider requesting authorization of the medical assistance;
- c. Date of the request for authorization;
- d. Statement of reasons for the denying the services;
- e. Reference to a basis for the decision (such as a formulary, rule or plan provision);
- f. Information about the opportunity to contest the decision;

g. Instructions on how to contest the decision, including the right to expedited process concerning urgent care;

h. An explanation of the circumstances under which on-going medical services are continued if a hearing is requested.

4. Receipt. Receipt of any notice shall be presumed to be five (5) days from the date of mailing unless it is demonstrated that receipt was more than five days after mailing. An action is deemed completed if deposited with the U.S. Postal Service or other commercial mail carriers by the last date for action.

5. Appeal Rights. Enrollees shall:

a. Have the right to appeal actions by MCOs or BHOs denying, terminating, suspending, or reducing medically necessary medical services and the right to request TennCare, in writing, for a reasonable and appropriate directive to the MCO or BHO to provide coverage of a service based upon the BHO or MCO's failure act in a timely manner;

b. Be allowed no less than 30 days from receipt of written notice to appeal any adverse action affecting requests for medical assistance;

c. Appeal in writing. Reasonable accommodations will be made for persons with disabilities who require assistance with their appeal, such as an appeal in person, by telephone, by TDD services or other communication device for people with disabilities; and,

d. Have appeals resolved by hearing and a written hearing decision within 90 days from the date the appeal is received. It is the intent of the parties, however, that

cases involving urgent care or continuation of benefits should be accomplished, where possible, as expedited appeals.

6. Hearing Rights. Enrollees shall be entitled to a hearing before an impartial hearing officer or administrative judge that affords enrollees the rights to:
  - a. representation at the hearing by anyone of their choice, including a lawyer;
  - b. review information and facts relied on for the decisions by the MCO or BHO and the TennCare Bureau before the hearing;
  - c. Cross-examine adverse witnesses;
  - d. Present evidence, including the right compel attendance of witnesses at hearings;
  - e. review and present information from their medical records;
  - f. present evidence at the hearing challenging the adverse decision by her or his MCO or BHO;
  - g. ask for an independent medical opinion;
  - h. continue or reinstate ongoing services pending a hearing decision as specified in Section II (9), *infra*; and
  - i. a written decision setting out the hearing officer's or administrative judge's rulings on findings of fact and conclusions of law.

7. An independent hearing officer is an individual who is not an employee, agent or representative of the MCO or BHO and did not participate in, nor was consulted about, any TennCare Bureau review prior to the hearing. Consistent with the Code of Judicial Conduct, hearing officers and administrative judges shall assist *pro se* enrollees in developing the factual

record; they shall have authority to order second medical opinions at no expense to the enrollee.

8. Review of impartial hearing officer's and administrative judge's decisions shall be available pursuant to the Tennessee Administrative Procedure Act, Tenn. Code Ann. § 4-5-301, et seq.

9. Continuation of Services. Except as provided under 42 CFR 431.213, 431.214, and 431.220, medical assistance services shall continue until an initial hearing decision if the enrollee appeals and requests continuation of services within 10 days or 5 days, as applicable under §§ 431.213 and 431.214, of the receipt of the notice of action to terminate, suspend or reduce ongoing services. If an enrollee makes a timely request for continuation of the disputed services pending expedited appeal, and subsequently requests a continuance of the proceedings without presenting a compelling justification, the hearing officer or administrative judge shall grant a conditioned continuance. The condition of such continuance is the enrollee's waiver of his right to continue receiving the disputed services pending a decision if the hearing officer or administrative judge finds that such continuance is not necessitated by acts or omissions on the part of the State, MCO or BHO and the enrollee lacks a compelling justification for the requested delay. Since expedited appeals involve urgently needed services or continuation of ongoing services determined by TennCare as not medically necessary, it is the parties' intent that expedited appeals should be accomplished within the time deadline set forth in Exhibit B, and that such time frame should not be delayed except as ordered by the administrative judge or hearing officer.

10. Expedited appeal of any action denying urgent care must be available to enrollees as follows:

a. The enrollee or the enrollee's parent, legal guardian or representative and primary care provider or treating specialist physician attests that the enrollee requires urgent care;

b. An expedited appeal shall be resolved by hearing and a written hearing decision within 31 days from the date the appeal is received.

11. TennCare will direct notices of the right to appeal adverse decisions affecting services to be displayed in public areas of all providers participating in each MCO or BHO, of MCO or BHO facilities, of county health departments, and of county Department of Human Services offices.

12. A plain language explanation of appeal rights shall be provided to enrollees upon enrollment in MCO and BHO plans and periodically thereafter, but no less than annually.

13. "Plain language" means any notice or explanation that requires no more than a sixth grade level of education as measured by the Flesch Index, Fog Index or Flesch-Kincaid Index.

14. Pharmacy.

(a) Ongoing out-patient pharmacy services. Notice of termination or suspension of ongoing out-patient MCO authorized pharmacy services is provided by the pharmacist at the time the prescription for out-patient pharmacy is presented. If the MCO is unable to respond to a medical necessity review on the day of the request or if the prescriber is unavailable, the MCO must provide a 72-hour supply of the prescribed medication, provided that: i) the medication is not classified by the FDA as Less Than Effective (i.e., a DESI, LTE or IRS drug); or ii) the medication is not a drug in a non-covered TENNCARE therapeutic category (e.g., appetite suppressants, drugs to treat infertility); or iii) use of the medication is not

contraindicated because of the patient's medical condition or possible adverse drug interaction. With regard to non-formulary medications, if the MCO is able to respond to a request for medical necessity review to continue the ongoing pharmacy services on the day of the request and the prescriber attests there is no formulary medication that is therapeutically equivalent and clinically efficacious, the MCO must continue to provide the prescribed medication pending the conclusion of an expedited appeal to the TennCare Bureau. Notice of appeal rights and opportunity to request continuation of services will be provided by the pharmacy.

(b) Initial requests for out-patient pharmacy services. If the MCO is unable to respond to a medical necessity review on the day of the request or if the prescriber is unavailable, the MCO must provide a 72-hour supply of the prescribed medication, provided that: i) the medication is not classified by the FDA as Less Than Effective (i.e., a DESI, LTE or IRS drug); or ii) the medication is not a drug in a non-covered TENNCARE therapeutic category (e.g., appetite suppressants, drugs to treat infertility); or iii) use of the medication is not contraindicated because of the patient's medical condition or possible adverse drug interaction; or, iv) (as the patient is not already taking the medication) use of the medication for a 72-hour period possibly followed by abrupt discontinuance of the drug would be medically contraindicated. Notice of Appeal Rights will be provided by the pharmacy.

19. Section IV is deleted and a new Section IV shall be inserted to read as follows:

#### **IV. ENHANCEMENTS OF APPEAL PROCESS**

1. The TennCare Bureau shall establish a central registry for all appeals by enrollees as described herein. The establishment of a central registry for BHO services may be delegated to the Tennessee Department of Mental Health and Mental Retardation. The purpose

of these registries is merely clerical. The appeal will be entered into a system for tracking and monitoring, and will be referred to the appropriate MCO or BHO.

2. Upon receipt of an appeal by an enrollee concerning medical assistance other than urgent care, the appeal shall be timely processed in accordance with the "TennCare Appeal Process" attached as Exhibit A and incorporated by reference. The parties recognize that the time frames, other than the 90-day standard under 42 CFR 431.244(f), reflect the Department's monitoring authority and do not establish enforceable obligations of the defendant state officials. In the system for processing appeals, the step which involves reassessment by the MCO or BHO can be eliminated, as can internal TennCare Bureau review, should the Bureau decide to do so.

3. Upon receipt of an appeal from an enrollee that concerns urgent care, the appeal shall be timely processed in accordance with the "TennCare Expedited Appeal Process" attached as Exhibit B and incorporated by reference. Cases involving continuation of benefits may also be processed by the Department as expedited. The parties recognize that the time frames, other than the 90-day standard under 42 CFR 431.244(f), reflect the Department's monitoring authority and do not establish enforceable obligations of the defendant state officials. In the system for processing appeals, the step which involves reassessment by the MCO or BHO can be eliminated, as can internal TennCare Bureau review, should the Bureau decide to do so.

4. The failure of an MCO or BHO to meet the deadlines set forth in Exhibits A and B for completion of reassessment and notification of the enrollee shall result in a resolution of the appeal in favor of the enrollee.

5. The failure of the MCO or BHO to act timely on a request for prior authorization or approval shall result in a favorable resolution of the enrollee's appeal.

6. If an initial hearing decision is not issued by the 90th day, and if the enrollee so elects, the service will be provided until an initial order issues denying the request. The 90 day computation excludes delays attributable to the actions or omissions of the enrollee, or the enrollee's representative. TennCare may, at any time, apply to the hearing officer or administrative judge to stay or cease this deemed approval coverage of the service upon a showing of good cause, including, for example, that the service is clearly non-covered under federal or state law (e.g., routine dental care for adults). This conditional authorization upon the 90th day will neither moot the pending appeal nor be evidence of the enrollee's satisfaction of the criteria for disposing of the case, but is simply a compliance mechanism for disposing of appeals within 90 days. If the initial and the final order uphold the denial, TennCare or the MCO may institute recovery procedures against the enrollee to recoup the costs of any services furnished to the extent they were furnished solely by reason of this section. The parties further recognize that TennCare reserves the authority to withdraw this compliance mechanism by state administrative rulemaking authority.

7. In the event that the enrollee prevails at any stage of the appeal process, the MCO or BHO shall be liable for the cost of care received from network or authorized provider(s).

20. Section V has expired by its terms. Section VI is renumbered V. Section VII is deleted and a new Section VII shall be inserted to read as follows:

## VI. MONITORING

1. Defendants shall provide plaintiffs' attorneys copies of all defendants' standard operating procedures, revisions to standard operating procedures, defendants' requests for approval by HCFA of risk agreement revisions, defendants' requests for additional waivers or clarification of waivers by HCFA, additions, revisions, updates or clarifications to risk agreements and waivers by HCFA, and actual revisions to risk agreements, if they pertain to the appeals procedure under TennCare.

2. For six full calendar months following entry of these modifications, the State defendants shall compile from the appeal central registry monthly reports indicating the number of appeals by MCO or BHO, the type of care, the number of days for resolution of the appeal, type of resolution (reversal or affirmance after reassessment by MCO or BHO; reversal or affirmance after review by TennCare of TennCare Partners; reversal or affirmance after hearing). These monthly reports shall be provided to plaintiffs' counsel.

3. Following the sixth month central registry report, the parties shall meet to review the reports and to recommend modifications, if any, to the appeals process under TennCare.

4. Upon 30 days prior notice, plaintiffs' counsel shall have access during normal business hours to any public records maintained by the TennCare Bureau and TennCare Partners. Subject to any applicable federal laws limiting the authority of a court to grant access to such records, plaintiffs' counsel shall have access to the records of members of the plaintiff class. All names and addresses of plaintiff class members provided to plaintiffs' counsel shall be considered to be confidential and shall not be used for functions other than those directly related to compliance with the modified Second Consent Decree.

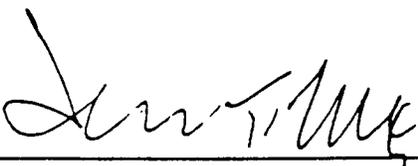
21. Implementation

Defendants shall implement the modifications herein within 60 days of the entry of this order. Upon certification by the appropriate official(s) that the modifications herein have been implemented, the injunction issued by order entered on May 15, 1996 (Doc. No. 377) shall be lifted. The parties recognize that the Department(s) may change any implementing U.A.P.A. Rules or Regulations so long as they remain consistent with this Court's May 15, 1996 order.

22. Defendants shall pay all allowable costs, including plaintiffs' reasonable attorneys' fees pursuant to 42 U.S.C. § 1988, since the Second Consent Decree and for services rendered which directly relate to monitoring compliance issues resolved in these Modifications to Second Consent Decree which have accrued up to the date of entry of the modified decree.

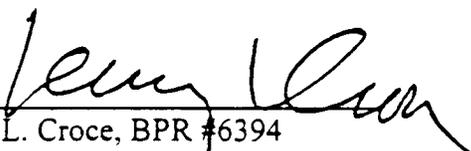
23. The parties shall make a good faith effort to resolve and settle the question of amounts of plaintiffs' attorneys' fees and other costs before submitting that issue to the court for resolution. Within 60 days of entry of the modified decree, plaintiffs' counsel shall submit itemizations of fees and expenses to defendants' counsel. If the parties cannot reach a resolution and agreement, plaintiffs' counsel shall submit affidavits and itemizations of attorneys' fees and expenses to the court within 120 days of entry of the modified decree. Defendants shall file objections to the fees request within 60 days of plaintiffs filing the affidavits and itemizations. These time periods may be extended by the court for good cause shown.

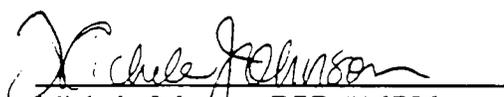
Enter this <sup>26</sup> ~~26~~ day of <sup>August</sup> ~~July~~, 1996.

  
\_\_\_\_\_  
John T. Nixon, District Judge

APPROVED FOR ENTRY:

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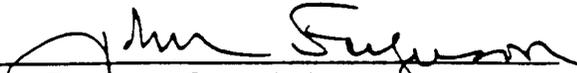
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TENNESSEE DEPARTMENT OF FINANCE AND ADMINISTRATION

  
\_\_\_\_\_  
John Ferguson, Commissioner

  
\_\_\_\_\_  
Theresa Clarke, Administrator  
TennCare Bureau

## TENNCARE APPEAL PROCESS

<u>DAY</u>	<u>DESCRIPTION OF TASK OR EVENT</u>
0	Enrollee's appeal from notice of MCO or BHO denial, termination, reduction, suspension or delay received at central registry.
7	Appeal keyed into database and referred to MCO or BHO for reassessment. Office of General Counsel (OGC) notified of appeal.
10	Enrollee's appeal received by MCO or BHO.
24	MCO or BHO completes reassessment and sends letter affirming decision or reversing decision to enrollee with copy to TennCare or TDMHMR Grievance Intervention Team (GIT).
29	MCO or BHO reassessment letter received at TennCare or TDMHMR GIT.
34	OGC notified to schedule fair hearing.
39	Notice of fair hearing to enrollee and representative, if any.
59	TennCare or TDMHMR GIT completes review.
80	Fair hearing held.
90	Hearing decision issued.

Days are intended to represent calendar days. If the deadline falls on a Saturday, Sunday or holiday, the task or event must be completed by the next business day.

### EXHIBIT A

## TENNCARE EXPEDITED APPEAL PROCESS

<u>DAY</u>	<u>DESCRIPTION OF TASK OR EVENT</u>
0	Enrollee's appeal from notice of MCO or BHO denial, termination, reduction, suspension or reduction received at central registry.
5	Appeal keyed into database and referred to MCO or BHO for reassessment. Office of General Counsel (OGC) notified of appeal.
8	Enrollee's appeal received by MCO or BHO.  Notice of fair hearing to enrollee and representative, if any, and provider.
13	MCO or BHO completes reassessment and sends letter affirming decision or reversing decision to enrollee with copy to TennCare or TDMHMR Grievance Intervention Team (GIT).  TennCare or TDMHMR GIT completes review.
28	Fair hearing held.
31	Hearing decision issued.

Days are intended to represent calendar days. If the deadline falls on a Saturday, Sunday or holiday, the task or event must be completed by the next business day.

### EXHIBIT B